Government of West Bengal

Department of Health

Report

of the

Drugs Enquiry Commission

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Chapter I

1.1. GENESIS OF THE ENQUIRY

1. "The Statesman", a Calcutta daily, quoting a P.T.I. message from Bangalore of July 26, 1962, stated that the Drug Control Administration of Mysore had siezed 40,000 ampoules of distilled water for injection and other injections like Milk Protein and Dextrose. The ampoules bore the mark of firms outside the State and were suspected to have been manufactured by unlicensed firms. Samples analysed by the Government of India in Central Drugs Laboratory, Calcutta, declared them unfit for human use as they contained impure and suspended matters. "Drugs manfactured by 16 firms situated outside Andhra were frozen in Hyderabad by the State Drug Controller, pending further investigation."

2. The same paper followed it up by another news on 27th July 1962, which besides briefing the State Drug Control Administration contended that the reported seizure of a large number of ampoules containing sub-standard listilled water in Maharashtra and Kerala had shocked the local druggists and that "not only sub-standard distilled water, many spurious drugs too find their way into the market, endangering the health of the people." The same day another news from Bombay was headlined quoting a Press Trust of India message that the Maharashtra Drug Control Administration had cautioned physicians, chemists, druggists and pharmaceutical firms all over the State against using or selling three types of drug—Aminophylline, Glucose and Atropine injections—believed to have been imported from West Bengal. The same headline further paragraphed that the Drug Control Administration of Maharashtra had frozen one million units of these three different drugs during two months after surprise inspections of pharmaceutical firms there.

3. The same day the West Bengal Chief Minister announced on the floor of the Legislative Assembly that "Government have decided to appoint a Commission to enquire into the drug manufactures in West Bengal with special reference to spurious drugs. The Chairman of the Committee will be Sri Biren Mookherjee, the other members of the Commission will be—

(1) Dr. B. P. Tribedi,
(2) Dr. Kanak Sarbadhikari, Principal, Medical College, Calcutta,
(3) Dr. Salil Dutta of the Indian Medical Association,
(4) Dr. Abodh Sinha,
(5) Dr. Ashima Chatterjee,
(6) The Commissioner of Police, Calcutta, and
(7) The Director of Health Services.

we have kept the ninth seat vacant".

4. The Health Minister of West Bengal made the following statement:

"It appears from the newspaper item published in "The Statesman", dated 27th July 1962, that Drug Control Administration of the Government of Maharashtra has cautioned physicians, chemists, druggists and pharmaceutical firms all over the State against using and selling of the following drugs: (1) Aminophyllin, (2) Glucose and (3) Atropine injections which are believed to be manufactured by some firms of West Bengal and imported therefrom.

"Wire has been issued to the Drug Controller, Maharashtra, to intimate the names of the firms suspected to have manufactured above drugs as no communication over this has yet been received by the Drug Control Administration of this State. Action against the delinquent firms will be taken by the Drug Control Administration of this State, on receipt of the reply from the Director, Drug Control, Maharashtra. Even today another wire has been sent.

"The Drug Control Administration of this State holds periodical inspections and raids in collaboration with the Enforcement Branch of Police for checking manufacture and sale of sub-standard and misbranded drugs. Such actions are also taken on receipt of complaints from other States as well as from persons in and outside the State.

"In respect of water for injection the Drug Control Administration of this State has prosecuted the following six firms:

(1) Bengal Pharmaceutical Industries,

(2) Vitamin Laboratories,

(3) Aryan Chemical Works,

(4) Chandulall Bros.,

(5) Raspin Pharmaceutical & Co., and

(6) International Drug House.

These firms have been prosecuted for sale and manufacture of sub-standard 'water for injection' and two of these cases (Bengal Pharmaceutical Industries and Vitamin Laboratories) have ended in conviction and these two firms do not now own licence under the Drugs Act for manufacture of any drug.

"Cases against other 4 firms are proceeding. Samples of 'water for injection' of seven firms have since been seized and sent for analysis. On receipt of the report action will be taken under the Drugs Act against the delinquent firms, if any. Complaints about sale of sub-standard 'water for injection' stated to have been manufactured by the firms (Aryan Chemical Works and Bengal Pharmaceutical Industries) were received from Maharashtra in the recent past. A reply was sent to the Drug Control Administration of Maharashtra stating that Messrs. Bengal Pharmaceutical Industries do not own licence for manufacture of any drug since 1952. Two raids with the help of Police were organised and held on the premises where the firm was formerly located, but no trace of manufacture could be found out at the said address. All the State authorities have been alerted about the position of this firm. Cases against Messrs. Aryan Chemical Works have already been taken up and hearing is proceeding.

"With regard to manufacture of Glucose solution, no complaint appears to have been received from any quarters. In course of regular inspection held by the Inspectorate Staff of the Drugs Control Administration of this State a few samples were collected from different firms and sent to the State Drug Analyst for testing and analysis. The reports are awaited.

"In respect of Atropine injection and Aminophyllin and Normal Saline no complaint has been received from any quarter in the recent past. The honourable members are aware that the Chief Minister had announced yesterday the appointment of a high powered Commission on the subject and their findings are awaited."

5. Shri Jyoti Basu, leader of the Opposition, speaking in Bengali, stated on the 30th July 1962 that large quantities of medicines and injections which proved to be spurious or sub-standard on examination, were seized by the Drug Control Administration of Maharashtra and Kerala. He said that he had specifically asked, if these were being sold in West Bengal also as neither the public nor the doctors were aware that drugs were spurious. He stated that according to the newspaper report, the matter had been discussed in the Maharashtra Legislature also. He alleged that Government was keeping back certain information from the House.

6. The late Dr. J. R. Dhar, Health Minister, replying in Bengali stated that he had sent telegrams to Bombay but had received no reply and that the Maharashtra Deputy Minister had stated that investigations were being continued by them and they could not disclose the names.

7. Dr. A. A. Md. Obeidul Ghani, another member of the Legislature, stated that serious allegations had been made against the State of West Bengal and that Calcutta Chemicals had complained that unless the names of these spurious firms were made public, greater harm would be caused.

8. The late Dr. Jiban Ratan Dhar made another statement in following terms:

"In May last the Director of Health Services, Madhya Pradesh, sent a list of 13 manufacturing concerns located in the State of West Bengal, to find out whether they had valid licenses. Accordingly full details of each of the firms, giving the standard of their manufacturing process and whether or not they held a licence, were forwarded. Similar information was given to other States on receipt of their enquiry.

"Six out of these firms were proceeded against for manufacture of sub-standard drugs, two of them have already been convicted by the Court. These cases were launched long before any intimation from other States was received about supply of sub-standard drugs by them.

"Government of Maharashtra have intimated by telegram and telephone, in response to our request to further elucidate their feelings, that they have detected sub-standard drugs in respect of products manufactured by four firms, viz.:—

(1) Aryan Chemicals,

(2) United Drug House,

(3) Carbon Laboratory, and

(4) A. C. Chakravarti & Co.

two of which are those against whom we have already launched prosecutions. The items of preparations indicated by them are the following:

(1) Normal Saline,

(2) Distilled Water,

(3) Glucose,

(4) Aminophylline,

(5) Calcium Carbonate, and

(6) Atropine.

further investigations are in progress in respect of the other two firms in direct communications with the Government of Maharashtra.

"In every case where a sub-standard drug is found after due testing prosecution is launched against the firms and all products of that particular batch are seized, but no notification is, however, possible until actual conviction by the Court. Only in one case so far the conviction has been upheld by the High Court and necessary action is being taken to notify the public about this. So, far, 262,300 ampoules have been seized as a result of our investigation.

"The following firms have been prosecuted for manufacture of sub-standard preparations on the dates noted against each:

(1) Aryan Chemical Works—5th October 1961,

(2) United Drug House—June 1961,

(3) Vitamin Laboratories—10th May 1960,

(4) Glucol Products Pvt. Ltd.—14th June 1961,

(5) Bengal Pharmaceutical Industries—Offenders convicted and appeal dismissed by the High Court, and

(6) International Drug House Pvt. Ltd.—9th December 1961,

of these, the conviction of Bengal Pharmaceutical Industries had been upheld by the High Court in respect of sub-standard water for injection.

"Section 35 of the Durg Act, 1940, lays down that it shall be lawful for the Court before which the conviction takes to cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published. In view of this, so far immediate publication of seized batches of drugs has not been customary. Necessary action has, however, been taken to evolve a method so that in addition to seizing the particular batches of the preparation, the profession and the public may be warned against further use of these particular products."

9. On 5th September 1962 in reply to Lok Sabha question No. 2297 by:

Shri Umanath,

Shri Yashpal Singh,

Shri Bagri,

Dr. R. Banerjee,

Dr. P. Srinivasan,

Shri Ram Ratan Gupta,

Shri Subodh Hansda,

Dr. P. N. Khan,

Shri Rabindra Varma,

Shri Vishwanath Panday, and

Shri A. N. Vidyalankar,

asking for information on—

(a) whether Government would lay a statement on the table detailing facts of freezing of common ampoules and spurious drugs in various States in the months of June and July 1962 stating the names of States, name of drug, or ampoules and the extent seized:

(b) whether the sources of these spurious manufacturers have been traced;

(c) if so, their names; and

(d) what action has been taken by the State Government and Central Government for a probe and to check their manufacture;

the Minister of Health (Dr. Sushila Nayyar) stated—"(a) to (c): A statement detailing facts of freezing of common ampoules and spurious drugs in various States in the months of June and July 1962 is laid on the Table of the House. Placed in Library. See No. LT-427/62. (d) The Central Government have advised the State Drugs Control Authorities to prosecute the manufacturers and move the Courts for confiscation of the seized stocks. The following actions have been taken by the different Governments:

Andhra.—Provisions under section 32(3) of the Drugs Act were invoked in respect of 10 firms and immediate instructions were issued to the Drug Inspectors of the State to be alert in freezing the stocks and sending the samples to the Institute of Preventive Medicine, Hyderabad, for analysis. All the District Medical Officers and the Superintendents of Government Hospitals including private medical institutions were informed not to use the drugs manufactured by the 16 firms, the names of which were furnished by the Drugs Controller (India).

Bihar.—The detailed reports in respect of Drugs and Ampoules seized during the month of July 1962 are awaited. On receipt of the analytical reports from the Government analyst necessary action against the persons concerned will be taken under the Drugs Act and the Rules thereunder.

Jammu and Kashmir.—No action has been taken as no complaints about the sale of such drugs have been received.

Madhya Pradesh.—The State Government is examining the matter.

Madras.—The sale of spurious drugs has been prevented by freezing and seizure of stocks held by the dealers in the State. The Government Medical Officers have been warned. The Drug Inspectors of the Districts have been alerted in the matter and the Government Analysts have been instructed to give top priority to the analysis of the spurious drugs.

Mysore.—The Drugs Control Administration has been exercising vigilance in this matter and the Inspectorate staff have been further alerted in the matter.

Maharashtra.—The State Government propose to take legal action against the defaulting firms in the State. The matter has also been reported to the authorities in West Bengal for further action against the manufacturers. As soon as the investigations are completed prosecution under the Drugs Act, 1940, will be instituted against all the persons concerned in that State.

Orissa.—Samples of drugs have been sent to the analytical laboratory for tests. Further action will be taken on receipt of the report.

Punjab.—Seized ampoules of distilled water have been kept under the custody of the Inspector and the position brought to the notice of the Drugs Controller (India) for taking necessary action against the manufacturers.

Rajasthan.—The Drug Controller, Rajasthan, has already issued a circular to all Administrative Officers of Hospitals in the State to send one sample of distilled water ampoules of each batch out of the supplies made by the approved suppliers for this year as well as last year to the various hospitals and dispensaries to the Government Analyst for analysis. The Drug Inspectors have been advised to check the stocks of various Chemists and Druggists to find out if they stock distilled water manufactured by certain unlicensed firms of West Bengal and if so they should seize the same and take samples thereof for analysis by the Government Analyst.

Kerala.—All the spurious drugs have been frozen and the matter reported to the Drugs Controller (India) and the Drugs Licensing Officer, West Bengal. The Kerala State Government have appointed an Intelligence Branch attached to the Drugs Control Department and a full time Drug Inspector in charge of this section for checking the manufacture, sale and distribution of spurious and sub-standard drugs.

West Bengal.—A Commission is being set up for enquiry into the Drug manufacture in West Bengal with special reference to spurious drugs. So far prosecution has been instituted against one firm for manufacture of sub-standard drugs.

Himachal Pradesh.—Necessary action in the matter will be taken on receipt of the result of the samples seized on the basis of reports in other States.

Tripura.—Nil.

Delhi.—The Report of Government Analyst has been received in one case which has been reported not of standard quality. A show cause notice is being issued to the firm from whom samples were taken. Action regarding rest will be taken on the receipt of the report of the Government Analyst.

Lacadive Administration.—Nil.

Manipur.—Nil."

1.2. NOTIFICATION

10. The Drugs Enquiry Commission was constitued under the Commission of Enquiry Act (LX of 1952) of Notification No. Medl/12199/3C-88/62, dated 22nd September 1962.

Terms of reference

11. The terms of reference of the Commission are:

(i) the manufacture of drugs in West Bengal by companies, organisations or individuals, whether on a small scale or large scale with special reference to the following points, namely:

(a) procurement of suitable plants, machinery, equipments and raw materials locally or by import at reasonable prices;

(b) adequacy of financial resources of those engaged in the Drugs Industry;

(c) provisions and safeguards for checking the suitability of materials used and ensuring during the process of manufacture, that the drugs conform to prescribed standards;

(d) employment of duly qualified technical expert to supervise the process of manufacture in order to ensure that the drugs conform to prescribed standards;

(e) measures adopted by manufaucturers for testing the suitability of drugs before placing them in the market;

(f) difficulties, if any, faced by the manufacturers in producing drugs conforming to prescribed standards;

(g) the extent to which existing taxes, duties and fees adversely affect the Drugs Industry, if at all;

(ii) adequacy of the existing laws in controlling by licenses or otherwise the manufacture, testing storage, distribution and sale of drugs with particular reference to the administration of such laws and the working of the State Drugs Testing Laboratory and the State Drug Control Organisation and deficiencies, if any, in such laws or in the administration thereof;

(iii) the extent of malpractices in the matter of manufacture, storage, distribution and sale of drugs, the reasons therefor and the ways and means of prevention thereof;

(iv) adequacy of production, supply and distribution of drugs with reference to the demand and whether inadequacy and shortage in the supply has in any way encouraged the manufacture of spurious and sub-standard drugs;

The Members of the Commission

12. The following were appointed Members of the Commission:

(1) Sri Biren Mookherjee,

(2) Dr. B. P. Tribedi,

(3) Dr. Kanak Sarbadhikari,

(4) Dr. Salil Dutta,

(5) Dr. Abodh Kumar Sinha,

(6) Dr. (Mrs.) Ashima Chatterjee,

(7) Dr. K. N. Sen

(8) Shri S. M. Ghosh, I.P., J.P.,

(9) Shri S. M. Banerjee, I.A. & A.S., and

(10) Shri R. Banerjee, I.A.S.

Sri Biren Mookherjee, M.A., (Cantab.), M.I.E. (India) was appointed Chairman to the Commission.

13. This is the first Commission constituted under the Commission of Inquiry Act in West Bengal for enquiring into, among other things, adulteration of drugs.

Composition of the Commission

14. The composition of the Commission by profession and professional qualifications is given below:

(1) Sri Biren Mookerjee, M.A. (Cantab.), M.I.E. (India), Governing Director, Martin Burn Ltd., Chairman, Board of Directors of Messrs. Indian Iron & Steel Co. Ltd., Indian Standard Wagon Co. Ltd., Burn & Company Ltd., Hooghly Docking & Engineering Co. Ltd., and other organisations.

(2) Dr. (Mrs.) Ashima Chatterjee, D.Sc., P.R.S., F.N.I., Khaira Professor of Chemistry, University of Calcutta.

(3) Dr. B. P. Tribedi, M.B. (Cal.), D.B. (Lond.), F.N.I., F.S.M.F., President, Indian Medical Association.

(4) Dr. Kanak Sarbadhikari, M.B. (Cal.), F.R.C.S. (Edin.), F.R.C.S. (Eng.), Principal, Medical College, Calcutta.

(5) Dr. Salil Dutta, M.B., D.T.M. & H. (Eng.), Vice-President, Indian Medical Association (Calcutta Branch), The Joint Secretary, Indian Medical Association (Central).

(6) Dr. Abodh Kumar Sinha, F.S.M.F., Lecturer in Pharmacology, Calcutta National Medical Institute.

(7) Shri S. M. Ghosh, I.P., J.P., Commissioner of Police, Calcutta.

(8) Dr. K. N. Sen, M.B., D.P.H. (Lond.), M.R.C.P. (Edin.), Professor of Pharmacology, Calcutta Medical College.

(9) Shri S. M. Banerjee, I.A. & A.S. (Retd.).

(10) Shri R. Banerjee, I.A.S.

15. Unlike American Model, the non-technical status of the Commission gave it an advantage, viz., the Commission like a body of judicial officers could examine experts and weigh their evidences free from predilections.

1.3 Commission of Inquiry Act: Ombudsman: Open Enquiry: Public Confidence

16. The Commissions of Inquiry Act was enacted more or less on the lines of English Tribunals of Enquiry (Evidence) Act, 1921.

17. Since Independence Government appointed Commissions and Committees with assignments under Sxecutive Order to enquire into matters of public interest and importance. But there was no legislation to regulate powers of such Commissions or Committees for enforcing the attendance of witnesses and for production of documents. Ad hoc legislation was resorted to from time to time like the Sugar Crisis Enquiring Authority Act, 1950. To meet the demand either by the Legislature or from the public for independent open enquiry the Commission of Inquiry Act, 1952 (Act LX of 1952), was enacted by Parliament.

18. The Act provided that "(1) the appropriate Government may, if it is of opinion that it is necessary so to do, and shall if a resolution in this behalf is passed by the House of the People or, as the case may be, the Legislative Assembly of the State, by notification in the Official Gazette, appoint a Commission of Inquiry for the purpose of making an inquiry into any definite matter of public importance and performing such functions and within such time as may be specified in the notification, and the Commission so appointed shall make the inquiry and perform the functions accordingly.

"Provided that where any such Commission has been appointed to enquire into matters:

(a) by the Central Government, no State Government shall, except with approval of the Central Government, appoint another Commission to enquire into the same matter so long as the Commission appointed by the Central Government is functioning;

(b) by a State Government, Central Government shall not appoint another Commission to enquire into the same matter or so long as it is functioning unless the Central Government is of opinion that the scope of the inquiry should be extended to two or more States."

Section 4 of the Act vests a Commission with the following powers of a Civil Court, trying a suit under the Code of Civil Procedure (1908):

(a) summoning and enforcing the attendance of any person and examine him on oath;

(b) requiring the discovery and production of any document;

(c) receiving evidence on affidavits;

(d) requisitioning any public record or copy thereof from any Court or Office;

(e) issuing Commissions for the examination of witnesses or documents;

(f) any other matter which may be prescribed;

or place where the Commission has reason to believe that any books of account or other documents relating to the subject matter of the inquiry may be found and may seize any such books of account or documents or take extracts or copies therefrom subject to the provisions of Section 102 and Section 103 of the Code of Criminal Procedure, 1898, in so far as they may be applicable.

Section 5 specifies the additional powers which may be vested in a Commission by the appropriate Government and runs as follows:

"(1) Where the appropriate Government is of opinion that, having regard to the nature of the enquiry to be made and other circumstances of the case, all or any of the provision of sub-section (2) or sub-section (3) or sub-section (4) or sub-section (5) should be made applicable to a Commission, the appropriate Government may, by notification in the Official Gazette, direct that all or such of the said provisions as may be specified in the notification shall apply to that Commission and on the issue of such notification, the said provisions shall apply accordingly.

(2) The Commission shall have power to require any person subject to any privilege which may be claimed by that person under any law for the time being in force to furnish information on such points or matters as, in the opinion of the Commission, may be useful—for or relevant to, the subject matter of the inquiry.

(3) The Commission or any officer, not below the rank of Gazetted Officer, specially authorised in this behalf by the Commission may enter any building.

(4) The Commission shall be deemed to be a Civil Court and when any offence as is described in section 175, section 178, section 179, section 180 or section 228 of the Indian Penal Code is committed

in the view or presence of the Commission, the Commission may, after recording the facts constituting the offence and the statement of the accused as provided for in the Code of Criminal Procedure, 1898, forward the case to a Magistrate having jurisdiction to try the same and the Magistrate to whom any such case is forwarded shall proceed to hear the complaint against the accused as if the case had been forwarded to him under section 482 of the Code of Criminal Procedure, 1898.

(5) Any proceeding before the Commission shall be deemed to be a Judicial Proceeding within the meaning of section 193 of the Indian Penal Code.

(6) Statement made by persons to the Commission.

No statement made by a person in the course of giving evidence before the Commission shall subject him to or be used against him in, any Civil or Criminal Proceeding except a prosecution for giving false evidence by such statement; Provided that the statement—

(a) is made in reply to a question which he is required by the Commission to answer, or

(b) is relevant to the subject matter of the enquiry."

19. In Scandinavia the procedure is unofficial enquiry by a High Court following the Ombudsman Procedure. It is generally held that such an enquiry is incompatible with the principle of Ministerial responsibility in Parliamentary Democracy. In New Zealand, the Administration set up in 1962 a one-man Commission under Sir Guy Powels and it worked satisfactorily.

20. The advantage of Ombudsman procedure is that the risk of mud throwing and speculation is lessened. For important and confidential matters, presence of the Public and the Press could be dispensed with. The controversy that raged in the United Kingdom during the Vassel Case had raised misgiving as to the public reaction to exposure during evidence before a Commission. Government officials subjected to cross-examination may inadvertently say things or create impressions which might, when published, be considered derogatory to their prestige and integrity. The Commission felt that there is room for both the Ombudsman procedure as well as open Enquiry, and decided upon having an open session where scandalous transactions, laxity of administration and even lack of integrity on the part of men of high reputation could be compromised in the interest of the State. At every stage balance of advantage was weighed. Initially, the balance was definitely on the side of an open Enquiry and the Commission allowed the Press to report the Proceeding in their own manner. No attempt was made at any point of time to influence the Press.

21. Some heat was generated in interested circles over the statement by some witnesses. Associations passed resolutions condemning the attitude and endorsed copies to the Commission and the Chief Minister.

22. The Commission felt that they should take no notice of the controversy and maintained their neutral attitude. Witnesses continued to feel secure at the assurance that their statements before the Commission was privileged. At this stage the Commission reconsidered the question of allowing the Press and the Public to continue to be present.

23. The Commissioners felt that witnesses must be protected. So thereafter, the Press and the Public were kept out. Fortunately however, by then the Commission had completed examinations of most of the witnesses

from the Medical Profession. Public confidence was not visibly shaken for shutting out the Press, nor did the Press react unfavourably as they appreciated the Commission's point of view.

24. The Government left the framing of the rules of procedure entirely to the Commission. The Commission on its part followed the Law of Evidence in India as far as practicable, but did not completely shut out evidence which would be inadmissible in a Court of Law where the evidence appeared strongly probable or reasonable.

25. A question was raised if there should be any appeal against the findings of a Tribunal. The answer is obviously in the negative. The other question was what should be done if evidence indicated that there had been violation of rules, regulations and statutory provisions. The Commission made it clear that they had no executive function. But such cases were brought to the notice of the Health Department, Government of West Bengal.

1.4. Previous Enquiries and Commission

26. The First Commission was the Royal Commission of 1896 on Opium appointed by the Sovereign. In 1927 a resolution was adopted by the Council of State recommending immediate measures for control of indiscriminate use of drugs and for legislating for standardisation of preparations and controlling sale.

27. In August 1930, the Government of India constituted the Drugs Enquiry Committee with Col. R. N. Chopra as Chairman, to enquire into—

(i) import of impure and sub-standard drugs;

(ii) those manufactured in India; and

(iii) for recommending steps for controlling sale and manufacture.

The Committee recommended—

(i) Legislation for control of drugs and pharmaceuticals;

(ii) Establishment of Test Laboratories in the various provinces for controlling the quality;

(iii) A Central Laboratory for controlling the quality of imported drugs;

(iv) An expert referee—Central Drug Laboratory—for dispute between the States regarding samples;

(v) Appointment of an Advisory Body for carrying out the objective and the steps recommended;

(vi) Setting up a course of training for Pharmacist and prescription of minimum qualification for Pharmacists;

(vii) Compulsory registration of all patent and proprietory medicines and undisclosed formulae whether imported or not.

The Bhore Committee (October 1943) officially known as the Health Survey and Development Committee attempted to emphasise the need for a thorough overhaul of the profession of pharmacy in the country. The Committee, besides others recommended—

(i) Establishment of an All-India Pharmaceutical Council and Provincial Pharmaceutical Councils;

(ii) Legislations aimed to protect the public from incompetence and to safeguard the interests of Pharmacists to raise the professional standing of Pharmacists, engaged in the handling of drugs;

(iii) Measures for the maintenance of disciplinary control over the practice and profession of pharmacy;

(iv) Measures for registration of Pharmacists; and

(v) Fresh courses of study for Pharmacists.

29. In 1945, the Department of Planning and Development set up a panel with Col. Chopra as Chairman, for indicating what fine chemicals, drugs and pharmaceuticals should be manufactured in this country. The committee recommended drugs for production within the next five years and necessary steps. They also recommended manufacture of anti-biotics like Penicillin, Streptomycin and Anti-Malarials, synthetic and sulpha drugs, State aid to drug industry, and training of technical personnel.

30. After three years, the Central Government set up a panel for the pharmaceutical industry on the lines indicated in the Chopra Committee's report. The panel listed the raw materials indicating quantities and sources of supply, and recommended a change in the import policy of Government. They also recommended that some of the firms should be encouraged to manufacture Citric Acid, Phenoburbitone, etc. In 1953 the Ministry of Commerce and Industry by a resolution No. C1-1(12)/52, dated 14th February 1953, set up a Pharmaceutical Enquiry Committee with Col. Bhatia as Chairman. The Committee in its 402 page report made a comprehensive and thorough survey of Drug Industry and practice of pharmacy and made far reaching and valuable suggestions. The Commission have freely consulted this report and referred to it.

1.5. PROCEDURES

General Remarks Regarding Procedures

31. The Commission decided to examine witnesses from among those who deal with Drug from manufacture to consumption. They were selected from amongst those who answered the questionnaires as also those whose views in the Commission's opinion were worth considering even though some of them had not replied.

32. It was decided that evidence of the manufacturers would be taken after the Commission had visited some of the manufacturing premises and laboratories. Accordingly laboratories and factories of five manufacturers were visited by the Commission.

33. Replies to questionnaires were carefully analysed for selection of witnesses. Shri R. Banerjee, Member-Seretary, along with Dr. S. Dutta and Dr. K. N. Sen, Members, drew up the list of Medical Practitioners and Dr. A. K. Sinha, Shri S. M. Banerjee and Dr. (Mrs.) A. Chatterjee, Member, drew up the list from amongst others. The Commission examined the Commissioner of Excise, the Additional Secretary of Finance, Director of Health Services, West Bengal, the Assistant Drugs Controller, Government of India, Assistant Director of Health Services, Drugs, West Bengal, and other experts. The Chief Medical Officers of quasi-Government organisations like Eastern Railway, Corporation of Calcutta, Port Commissioners and Senior Medical Officers of industrial concerns like Indian Iron & Steel Co. Ltd. who consume large quantities of drugs, were also examined by the Commission. A number of wholesalers of drugs, retail chemists and druggists, and distributors of drugs for foreign firms were also examined.

In drawing up the lists of witnesses from the replies received, stress was mostly laid on personal experiences and suggestions for improvement of the drug industry. Medical practitioners, chemists and druggists, pharmacists and members of public from different areas in West Bengal, both urban and rural were examined for ascertaining condition prevalent in the State. In selecting manufacturing firms for example, the Commission decided that some established manufacturers with capital over Rs. 50 lakhs and smaller manufacturers should be examined for coverage of the industry as a whole. A representative section was examined.

34. The evidence of the witnesses was tape-recorded.

35. Initially the Commission attempted to have the evidence recorded by Stenographers. But it was felt that the Stenographers experienced difficulties in recording accurately because some of the witnesses spoke simultaneously in English and Bengali causing confusion. So tape-recording was considered the most suitable method for recording evidences. Through the courtesy of the Assembly Secretary the Commission obtained the services of an operator and, through the courtesy of the Health Secretary, Shri B. R. Gupta, I.A.S., the Commission obtained use of two Tape-recorders, one for evidence and the other for dictation of reports by the member—Secretary, who had to work late in the night when the services of Stenographers were not available.

36. The evidence of the witnesses was transcribed and three copies made. Two copies were sent to the witness for confirmation, who was requested to retain one copy for personal use and return the other copy to the Commission after signing each page and making such corrections as desired by him. A caveat was entered there that if no reply was received within the specified date it would be presumed that the evidence would be taken to have been correctly recorded and would form part of the records of the Commission.

37. It was not necessary for the Commission to administer oath to any of the witnesses nor was it necessary to issue summons as most of them readily appeared. A few did not conduct themselves uniformly before the Commission. Some appeared to be excited. Some appeared to get confused. Some were rather uncommunicative presumably being afraid of making statements which might displease their superiors in profession. But, by and large the evidence tendered was truthful. The Commission had reasons to believe that some of the witnesses were not speaking the truth but as the related matter was inconsequential the Commission took no serious notice of such prevarications.

38. In support of the Press it must be said that towards the beginning they focussed their attention on the deliberations of the Commission which were open, and as such some of the incidents were given head-line publicity. The newspapermen however behaved with considerable moderation and were of great assistance to the Commission throughout.

39. In addition to the selection of witnesses as above the Commission issued twenty-five insertions in the local Press inviting the general public to communicate to the officials of the Commission any matter relevant to the terms of the reference. They were also requested to give evidence before the Commission. At the beginning of each session, the Chairman assured every witness that he was fully protected under the Commissions of Inquiry Act. The Commission did not resort to the use of powers vested in it under the Commission of Inquiry Act for giving false evidence or disobeying the request to appear, only in one case one of the stockists refused to disclose details of accounts and submit statement regarding its profit and loss in

the trade. When told that he could be compelled to do so, he volunteered to send the papers and statements of accounts. As however, his trading accounts was not substantial in character the matter was not followed up.

40. The evidence of 186 witnesses which had been tape-recorded and transcribed has been compiled in Part III of this Report.*

1.6. QUESTIONNAIRES

Questions issued: Replies: Analysis

41. Separate questionnaires were drawn up for members of the Medical Profession, Manufacturers, Members of the Public and Pharmacists. In addition, Chemists and Druggists were also issued with questionnaires from time to time, specimen of questionnaires are given in Part III of the Report.*

42. They were designed to cover the terms of reference corollary to this basic consideration and relevant to the terms of reference other subjects were included for eliciting information on all aspects of drug.

43. In drawing up the questionnaires, the Commissioners were aware that some of top technical men were working in academic remoteness under conditions not conducive to normal development of applied research. Therefore the opinion of such persons was eschewed. Nevertheless some of them were separately addressed as and when necessary.

44. The Commission emphasised elaboration of the problems by different groups for acquainting themselves with prevalent conditions and lines of thought on the subject. The Commission was fully alive to the varying standard among different groups. The question of addressing in Bengali was eschewed as the questions would have been incomprehensible to most of them. For facility of comprehension, which is conditioned by knowledge of the language of address the standard was varied from questionnaire to questionnaire. It is a matter of gratification that only very few persons asked for elaboration and by and large the answers were intelligible.

45. An analysis of the replies in order of percentage of Nos. issued is given below:

Serial No.	Questionnaires issued to.	No. of questionnaires issued.	Last dates of issues of questionnaires.	Date of receipt of last reply.	No. of replies received.	Percentage of replies on issue.
1	Manufacturers* ..	234	14-11-62	15-10-63	225	96·15
2	Medical Practitioners	4,849	21-12-62	15-10-63	1,585	32·6
3	Pharmacists ..	1,940	29-12-62	29-4-63	521	26·8
4	Chemists and Druggists	288	7-1-63	22-2-63	201	69·7
5	Divisional Commissioners	2	29-12-62	9-1-63	2	100
6	Superintendents of Police	15	29-12-62	18-1-63	12	80
7	District Magistrates	15	29-12-62	12-6-63	11	73·3
8	D.I.G. of Police ..	3	29-12-62	7-2-63	2	66·6

*Part III of the Report not printed.

Serial No.	Questionnaires issued to.	No. of questionnaires issued.	Last dates of issue of questionnaires.	Date of receipt of last reply.	No. of replies received.	Percentage of replies on issue.
9	Dy. Commissioners of Police	5	27-11-62	17-4-63	3	60
10	Chambers of Commerce ..	7	18-12-62	13-3-63	2	28·5
11	Principals of Colleges ..	192	24-12-62	15-2-63	52	27
12	District Auditors ..	15	18-3-63	4-4-63	4	26·6
13	Educational Service ..	466	4-3-63	30-3-63	114	24·4
14	Sub-Dy. Magistrates, Sub-Dy. Collectors and Block Development Officers.	365	15-3-63	29-4-63	78	21·3
15	Dy. Magistrates and Dy. Collectors.	189	29-1-63	10-5-63	39	20·6
16	Munsifs	76	5-3-63	17-4-63	15	19·7
17	Officers of Registration Department.	175	22-3-63	2-5-63	33	18·8
18	Chemists and Biochemists ..	34	12-12-63	4-1-63	6	17·6
19	Members of Syndicate, Calcutta University.	23	29-12-62	2-1-63	4	17·4
20	Dy. Superintendents of Police	60	6-3-63	11-4-63	10	16·6
21	Chairmen and Vice-Chairmen of Municipalities/Dt. Boards.	207	14-12-62	18-6-63	32	15·4
22	Engineers	133	5-2-62	16-4-63	18	13·5
23	Presidents of Employees' Associations.	33	11-1-63	28-1-63	4	12·1
24	Learned Societies Presidents Bar Association, Editors.	73	12-1-63	2-2-63		10·9
25	M. L. C.	71	11-12-62	26-12-62	5	7
26	M.L.A.	215	12-12-62	15-1-63	14	6·5
27	Trade Unions	621	21-2-62	25-3-63	41	6·4
28	Subordinate Judges ..	36	28-1-63	15-2-63	1	2·7
29	M.P.	70	10-12-62	18-12-62	1	1·4
	Total ..	10,412	..	..	3,043	29·23

*Actually 246 questionnaires were issued, but only 234 were effective, because ten manufacturing units closed down and two ceased manufacturing.

46. The overall percentage of 29.23 though low was much above the percentage of replies received by the Press Commission. The Commission issued 11,780 questionnaires and received 318 replies, i.e., only 2.7 per cent. answered. [Vide report of the Press Commission (1954), Part I, page 4-5.]

47. The manufacturers co-operated with the Commission at all stages and the high percentage (96.15 per cent.) of replies is an indication.

48. Only nine firms did not reply. Initially replies were not received from four more. Through the courtesy of one of the Commissioners, Shri S. M. Ghosh, notices were served through the Calcutta Police. The result was immediate. Two firms could not be traced.

49. The Commission had considerable difficulty in selecting names of medical practitioners for issue of questionnaires. The Commissioners examined the list of Registered Medical Practitioners maintained under section 32 of the Bengal Medical Act (1914). The list is not up to date presumably because the medical practitioners have not notified change of addresses or the Registrar did not act under sub-section 2 of section 16. Although this is an extraneous matter, the Commission would like to invite the attention of Government to strict compliance with the provisions of the Bengal Medical Act (1914).

50. The Commission, had to reply on the latest issue of the Calcutta Telephone Directory for the correct address of the doctors to whom questionnaires were sent. Private enquiries were also made. Four thousand, eight hundred and forty-nine doctors were addressed. This was fairly heavy and for a new office very difficult. Therefore, the services of the staff of the Special Officer, International Boundary Demarcation were frequently utilised. With the questionnaires were sent self-addressed envelopes for which the Postmaster-General was kind enough to allot Permit No. C-1688, thereby obviating the difficulties of stamping the reply-envelopes. The Commission is grateful to the Postmaster-General for early issue of the Permit.

51. It is a matter of regret that younger Medical Practitioners did not fully reciprocate the courtesy extended to them, and many of them ignored the questionnaires. This lack of interest appears to be symptomatic of the attitude of the younger men in professions today. It is a matter of great satisfaction however, that almost all the senior medical practitioners replied and some even volunteered suggestions of their own. Among the younger group lack of interest was noticeable and there was neither any attempt to answer nor any desire on their part to assist. This attitude was also apparent during their cross-examination. In a few cases their knowledge of English appeared rather poor. So long as medical text books, medical bulletins and research publications, including Drug Control Orders are written in English only, the Commission felt a bit concerned over it. Perhaps the Universities and the authorities of the Secondary Board of Education may like to consider this matter and rectify the defects.

52. Another matter, though not strictly relevant to the terms of reference, engaged the Commission's attention in passing. The Secretary of the Indian Medical Association (West Bengal Branch) was kind enough to publish the questionnaires in their Journal and also undertook to issue them from the office. But this was a vain attempt. Most of the medical practitioners remained completely unconcerned. This was noticeable in the demeanour of some of the witnesses also. Drug Control and Spurious Drugs appeared to be a subject in which they were not professionally interested.

53. The number of replies from the Pharmacists was disappointing. Considering that there are four classes of Registered Pharmacists and that some of them, though not fully qualified, have been allowed to practice as Pharmacists because of their long association with Dispensing Chemists, this was not surprising. Some of them, however, appeared to have taken considerable interest and answered the questions intelligently.

54. The Members of Parliament also lagged behind. Only 1.4 per cent. replied. What is more surprising is that the Commission which was constituted on the basis of speeches in the Provincial Legislature, did not evoke interest among the legislators later, only 6.5 per cent. replying.

55. The response from the District Magistrates was equally disappointing as compared with District Superintendents of Police. Seven District Magistrates, 12 Superintendents of Police sent their replies. The seniormost officers, viz., the Divisional Commissioners, were kind enough to send replies as soon as received, but the replies of others like Presidents of Employees' Associations, Trade Unions, Chambers of Commerce, were equally disappointing.

56. The Commission elicited information from other State Governments on specific issues. Drug is not an isolated commodity within the bound of a State's territorial jurisdiction. Trade in drug is spread throughout the country. Its manufacture is daily developing and distribution is expanding. So, information and co-operation from other State Governments were sought. Letters were issued to the following State Governments:

(1) Kerala.

(2) Mysore.

(3) Delhi.

(4) Uttar Pradesh.

(5) Assam.

(6) Orissa.

(7) Madhya Pradesh.

(8) Punjab.

(9) Bihar.

(10) Rajasthan.

(11) Andhra Pradesh.

(12) Madras

(13) Maharashtra.

(14) Gujarat.

(15) Jammu and Kashmir.

Copy of the letter forwarded to the State Government:

"I beg to state that Drugs Enquiry Commission has been set up by the Government of West Bengal under the Commissions of Inquiry Act (Act LX of 1952). A copy of the notification is enclosed for favour of your perusal.

The Commission will be grateful if your Government can furnish information on the following points:

(1) Number of drug manufacturing concerns in your State.

(2) Number of Indian firms manufacturing drugs in your State in collaboration with foreign manufacturers ab initio or by repacking. The names of the manufacturers, collaborators and of Drugs with import bulk price and wholesale selling price in India may kindly be stated.

(3) Allotment of foreign exchange during 1959/60, 1960/61 and 1961/62 for import of plant, equipment machinery for the drug industry.

(4) System of licensing and number of cases instituted under the Drugs Act during 1959/61.

(5) Tax structure with reference to drug industry. I am also to request that the system of procurement of Drugs by the State Government for consumption in hospitals, dispensaries, etc., may also be stated.

The Commission has reason to believe that there have been in the past complaints regarding the standard of drugs manufactured in West Bengal and purchased by you. I am to request that the source of supply, the agent, the price and the exact nature of complaint may please be furnished to the Commission.

It is presumed that your Government brought the matter to the notice of the Medical and Public Health Department of West Bengal. If so, result of your representation may kindly be communicated, if there is no objection. The Commission assures that any communication made by you, which you think should be kept confidential, would be treated as such.

The matter may kindly be treated as most urgent."

No replies have yet been received from the Governments of—

(1) Orissa,

(2) Rajasthan,

(3) Bihar, and

(4) Jammu and Kashmir.

Thus, replies from other State Governments constituted 73.3% only over the number issued.

1.7. OFFICE ORGANISATION

59. The details of staff in the organisation of the Commission and the number of meetings attended by the individual Commissioners have been noted below. It is a matter of regret that Dr. B. P. Tribedi could not find time to be present at more sittings because of his preoccupations with the affairs of the Indian Medical Association, of which he is the President.

60. The staff of the Commission consisted of the following:

Assistant Secretary	1
Statistical Assistant	1
Head Assistant	1
Upper Division Assistant	2
Stenographer	4
L. D. Assistant	8
Typist	2
Peon	6

In the matter of sanction for staff, the Commission faced considerable difficulties. Staff was not sanctioned in time, resulting in considerable delay in the work of the Commission. Presumably Government went by

their usual yardstick and were reluctant to go beyond the departmental convention. Therefore, the Commission had to depend on outside assistance in clerical and secretariat work. Even when the work of the Commission was well under way, delays occured in staff sanction. They quoted the analogy of the Police Commission, which was neither relevant nor appropriate. However, in due course Government realised the enormity of special type of work involved and were prompt in sanctioning staff and funds.

62. The Commission was fortunate in securing accommodation in the mezzanine floor of the New Secretariat Buildings within three weeks of its constitution. The first meeting of the Commission was held in the Committee room of Messrs. Martin Burn Ltd., Sir Biren Mookherjee, kindly lent the use of the room for the Commission. Thereafter it was felt and recognised that the Commission should have its own office and own committee room. The Administrator of the Durgapur Project, Shri A. B. Ganguly, I.C.S., kindly vacated the mezyanine floor and also permitted the Commission to use some pieces of furniture, which was very helpful. The Commission are grateful to them.

63. Details of expenditure, office administration are given in Part III of the Report.*

64. Total number of meetings for examination of witnesses—24.

Total number of General Sessions—41.

		No. of meetings for examination of witnesses.	No. of General sessions.	Total.
1.	Sir Biren Mookherjee	15	38	53
2.	Dr. B. P. Tribedi	2	7	9
3.	Dr. Kanak Sarbadhikari	12	26	38
4.	Dr. Salil Dutta	22	38	60
5.	Dr. Abodh Kumar Sinha ..	23	39	62
6.	Dr. (Mrs) A. Chatterjee	17	31	48
7.	Shri S. M. Ghosh.	10	33	43
8.	Dr. K. N. Sen	21	34	55
9.	Shri S. M. Banerjee	24	41	65
10.	Shri R. Banerjee	24	27	51

Details are given in the Appendix in Volume II.*

*Part III and Volume II of the Report have not been printed.

Chapter II

2.1. HISTORY OF DRUG INDUSTRY

65. Disease is as old as life on earth. Disease forms have remained essentially the same through millions of years. The oldest known human specimen shows morbid bony growth on the femur. Study of mummies suggests presence of Arthritis, Poliomylitis, Tuberculosis of Hip Joint 4,000 years before Christ. Skin lesions in some of the mummies suggest the presence of small-pox as early as 1,100 B.C.

66. Evidence of treatment has been found in some of the skeletons. Trephining of skulls was one probably undertaken to drive the evil spirits away, as the earliest systems of medicine were based on the theory that disease is caused by evil spirits. The method of treatment was to devise means for driving the evil spirits away, physically or by witchcraft. Belief in witchcraft exists even to this day amongst tribes and in civilized countries also where modern system of medicine is practised "pari passu" with witchcraft. Even in European countries and in the United States of America medicine men practice magic cures and fabulous sums are earned by them. This shows the subconscious craze even in the enlightened human mind for magic remedies.

67. The earliest evidence of any scientific medicine being practised was in Egypt as revealed by papyrus, i.e., Kahum papyrus dating back to 4,000 B.C. They dealt with Gynaecology and Veterinary medicines.

68. The history of Indian medicines can be traced back to 800 B.C. Ayurveda, the Hindu system of medicine was part of the Atharba Veda. The classics of Indian medicine are treatises by Charaka and Sushruta (800 to 600 A.D.), primarily based on materials derived from the Vedic Period.

69. In Hindu system of medicine, the diagnosis was highly developed and classification of disease was elaborate. Sushruta mentions over eleven thousand diseases, and 760 vegetable drugs as well as drugs derived from animal and mineral origin. Pharmacopoeia is replete with elixirs for lengthening life, aphrodisiacs, poisons and their antidotes. In 600 B.C. hospitals were established in India—one thousand years before any similar institution was promoted elsewhere. Surgery was equally elaborate and number of surgical instruments were developed.

70. Ayurveda was divided into Etiology, Symptomatology, Materia, Medica and Therapeutics. There was a section for each disease dealing with treatment and dietetics. Surgery, Gynaecology and diseases of Ear, Nose and Throat were the specialities and were dealt with separately.

71. The earliest known Physician in Bengal was Shri Madhavkar (900 A.D.), whose treatise on Medicine was authoritative for a very long time. The medicines used in the Ayurvedic system were mostly herbal though some mineral and animal products were also used. Some of these herbal medicines are still in use and have been accredited as drugs of choice for certain diseases in the western system.

72. The Ayurvedic system dealt elaborately with the methods of preparation of drugs, but methods of standardisation and determination of potency were neglected. Methods specified in the texts were deficient from the point of view of maintenance of standard and correctness of process.

73. With the coming of the Muslims, Ayurvedic system of medicine receded to the background because of State patronage of the Unani System. Tabibs and Hakims replaced Kavirajas.

74. In due course the Unani System was replaced by the western system of medicine. Introduction of the latter can be traced to the time of Akbar, Bernier, a French traveller and doctor, came to India in 1656 and was probably the first doctor to practise European system of medicine in India. Of course, the system of medicine in Europe was not yet developed. Wider adoption of the Western system followed Dr. Hamilton, the Physician to Farukshiar, the Emperor of Delhi. Real start in the practice of Western medicine was given by Lord William Bentinck, Governor-General, when in 1835 he founded the Medical College in Calcutta.

75. By now urged by enlightened colonialism and new spirit the European powers made rapid advance in research of manufacture of drugs, General anaesthetics like Ether and Chloroform were discovered and manufactured. It was in 1638 that the wife of the Viceroy of Peru, Countess Chincon, drank the crude portion of the red bark of a tree, a remedy known to the Incas of Peru from time immemorial, which cured her of fever. The drug in crude form was used, till in 1817, when Pelletier and Caventu, two French Pharmacists, proved that the bark contained a bitter principle, an alkaloid which only had therapeutic value. Pasteur's work on microbes, and Alphanso Leveren's work on therapeutic action of quinine was the starting point of a new approach to the art of healing, viz., specific drug for specific disease.

76. In 1856, Young Perkins failed to synthesise quinine but landed upon synthetic dye which opened the door to chemotherapeutic agents and selective action of stains on different tissues and mooro-organisms. In Germany, capricious injection of Mathylene Blue into the veins of a living rabbit revealed colouring of the nerves only, and set the young physician Paul Enrlich assisted by his Japanese Bacteriologist Shiga on the trial which finally led to Salvarsan, a specific for syphillis, after 606 different arsenic compounds had been tried on trypanosomes.

77. The Ayurvedic and Unani Systems remained static as in the medieaval days. The attempt of the East India Company to revive study of Ayurvedic System by making it compulsory subject in the Sanskrit College (1814), Calcutta, failed.

78. The late Sir P. C. Roy prepared a few simple galenical of the British Pharmacopoeia in his house. This was the beginning of the modern pharmaceutical industry in the private sector, followed by Prof. T. K. Gajjar and Rajmitre B. D. Amin. The British Pharmacopoeia of that period contained a few monographs on galenical, phytochemicals and poultices. The Indian industry received a filip during the First World War.

79. With the end of war imports went up. Some of the plants and factories opened during the war were shut down. Those which continued adopted modern methods of preparation of Sera, Vaccines and Liver Extracts. In between the first and the second war, practice of medicine made considerable progress in the West. Best and Banting's discovery of Insulin at Toranto in 1921 and Domagk's (following Enrlich) discovery of sulpha drug, popularly known as Prontosil in the thirties are landmarks in the progress of Western science in the art of healing. Chemotherapy, Synthetic drug and discovery of Vitamins changed the approach to treatment of disease. One notable contribution of India was the discovery of Urea Stibamin by Dr. Sir U. N. Brahmachari for treatment of Kala-azar.

80. The Second World War gave another impetus to the industry. Demand from the Armed Forces and the public increased. Government assisted the industry in manufacturing alkaloids like Ephedrine, Santomin,

Strychine and opium alkaloids like Morphine, Codeine. Shark Liver Oil factories were established on the Madras coasts and in Kerala. In the Post-War period the industry made phenomenal progress all over the world.

81. Tincture.—Extract therapy had been replaced by synthetics, hormones and antibiotic products. Sir Alexander Fleming (1881—1955) opened the door to antibiotics which account for 70 per cent. money value of the total drugs produced and consumed all over the world. Pills have given way to capsules and parenterals. Phyto-chemicals and galenicals have not lost their therapeutic uses, but there has been a shift in emphasis.

82. The Second World War had given an impetus to the British Pharmaceutical Industry also. War in the East and loss of Cinchona plantations in the East Indies stimulated research in Synthetic Anti-Malarial drugs. Chemotherapeutic pharmaceuticals which were practically monopolilsed by Germany were not available to the Allies. So the manufacture of synthetics was started in U. K. Discovery of Penicillin also boosted up the pharmaceutical trade there.

83. The pharmaceutical trade in U.S.A. made similar progress during and after the second world war. Today U.S.A. accounts for three-quarters of the total production of Penicillin, and Streptomycine, and is practically the sole producer of broad-spectrum antibiotics like Tetracycline, Chlaramphenicol, Terramycine, Erythromycine.

84. Drug Industry in India has been lagging behind. Today, out of 125 large-scale industries, only 40 units manufacture from basic raw materials. Of these 21 are foreign concerns, 20 being in the State of Bombay, five are Government enterprises, three being in Bombay. Of the remaining 14 under private management, seven are in Calcutta, five in Bombay and two elsewhere.

85. Most of the Indian concerns in West Bengal bottle formulations of phytochemical and galenicals sometimes with doses of Vitamins and hormones.

86. A view is held that firms operating in collaboration with foreign manufacturers have impeded the development of Drug Industry.

87. In future all such agreements should be thoroughly scrutinised by Government and the following guiding principles adopted in permitting collaboration with foreign firms. The existing agreements should also be revised at the earliest opportunity to be in conformity with them:

(i) No foreign collaboration should be entertained only in respect of of cosmetic items such as tooth paste, Eau-de-cologne, shaving creams, etc.,

(ii) Generally, foreign collaboration should be allowed only when a firm is agreeable to commence with the manufacture of at least a few basic drugs from primary raw materials.

(iii) Permission may be granted for compounding of selected drugs on the basis of essentiality provided the firm agrees to complete its programme of manufacture of basic drugs within a specified period.

(iv) The scheme of licensing should, as far as possible, be so evolved as not to give a monopoly to any one firm, but keep competition alive. In approving schemes for the manufacture of basic drugs, care should, however, be taken to see that the production of the same drug is not taken up by too many firms.

88. The order of preference for foreign collaboration should be as follows:

(i) Products manufactured wholly in India from basic raw materials of mainly Indian origin.

(ii) Products for the manufacture of which the basic chemicals and/or intermediates as near to the basic chemicals as possible are imported;

(iii) Products in which the finished drugs are imported in bulk and processed into pharmaceuticals here and packed; and

(iv) Finished products imported in bulk and only repacked here for sale.

89. Ultimately there should be little scope for collaboration with foreign concerns of the type given under (iii) and (iv) above although, these might be necessary for a specified number of years to begin with.

90. The Commission is of the opinion that lack of initiative on the part of most of the drug manufacturers and absence of a firm Government policy are the principal reasons for the present plight of the West Bengal Drug Industry.

91. Government of West Bengal has paid little or no attention to the development of medicinal herbs, their exploitation and their economics. Nor did it address itself to the manufacture of intermediates and basic raw materials.

92. In its first Industrial policy resolution Government of India included the pharmaceutical industry as one of the eighteen for which planning and regulations were necessary. The Pharmaceutical Enquiry Committee was established in 1953 to report on the development of the industry. The Committee recommended production of certain essential drugs, and accordingly Government set up a Development Council for Drugs and Pharmaceuticals in 1955.

93. So far, the activity in the public sector was confined to:

1. Plants for extraction of Cinchona fabrifuge at State Government factories in Madavattam, Annamalai (Madras) and Mongpoo (West Bengal) opened in 1871.

2. Central Government Opium (Poppy Capsule) factory at Gazipur started in 1820 A.D.

3. Opium Alkaloid Factory started in Gazipur in 1942, producing codeine and its sulphates; and phosphates, acetate (B.P.) Sulphate (B. P.) and Tartarate (B.P.C.) of Morphine and Morphine Hydrochloride.

4. Shark Liver Oil Factories.—(a) In Maharashtra the Sasons Docks at Bombay started manufacturing shark liver oil in 1946 under the State Fisheries Department.

(b) In 1940, the Kerala Soap Institute, a Government under-taking, commenced production of both plain and fortified shark liver oil.

5. Production of Vaccines and Sera by the Central and the State Government Institutes.

94. In 1954 there were in West Bengal a total of 564 Drug manufacturing concerns. Of these 25 were large and medium and 539 small. In 1964 this number has dwindled to 239 in all.

95. The fall in employment in chemical industry in West Bengal has been very great as the following analysis will show:

Year.	No. employed in Industry (India).	No. employed in West Bengal.	$\frac{(L)}{L}$	b	$\frac{L'}{Lb}$
1946	25,176	11,415	·453	·334	1·36
1947	32,250	12,830	·398	·319	1·25
1948	32,605	13,116	·402	·312	1·29
1949	30,975	12,277	·396	·304	1·30
1950	34,591	12,696	·367	·299	1·23
1951	37,663	13,131	·349	·290	1·20
1952	41,455	13,507	·326	·287	1·14
1953	42,286	12,713	·301	·278	1·08
1954	45,837	13,586	·296	·271	1·09
1955	52,984	15,954	·301	·273	1·10
1956	57,414	15,618	·272	·261	1·04

96. Development of the drug industry can only depend on organised research. The researches should cover exploitation of indigenous raw material for the manufacture of intermediates and penultimate drugs which are now imported, manufacture of plants equipments and electronic testing apparatus.

97. Scientific research has its origin in the curiosity of the human mind and as such, cannot be regimented. It cannot be left entirely in the hands of Government. If research is to retain its freedom it should start in the University laboratories. It should also be conducted in the research institutions of the manufacturers. But, considering the present cost there is need for co-ordination and collaboration with research workers in other countries. A correct approach should be to maintain a relationship between the manufacturing concerns and the Universities. Government should also assist in such research.

2.2. Raw Materials

98. There are over 25,000 modern drugs in use. Study of procurement of suitable plants, machinery, equipment and raw materials for these is a highly technical and intricate subject. Commission do not have time to go into this. Drugs and manufacturing processes are undergoing continuous change. Research workers and pharmaceutical manufacturers are competing to outdate each other. Therefore, any detailed recommendation at any point of time would lose significance soon. The Commission have, therefore, of necessity, confined themselves to basic subject in broad details.

99. The drugs can be broadly classified as under:

(1) Antibiotics.
(2) Synthetics.
(3) Phytochemicals.
(4) Galenicals.
(5) Of Animal Origin.

These have been reclassified under the following heads for the purpose of this report:

I. Antibiotics,
II. Sulpha Drugs,
III. Anti-Tubercular Drugs,
IV. Anti-Leprotic Drugs,
V. Anti-Dysentric Drugs,
VI. Synthetic Anti-Malarials,
VII. Anaesthetics,
VIII. Anti-Diabetics,
IX. Anti-Pyretic and Analgesics,
X. Anthelminthics,
XI. Vitamins,
XII. Hormones,
XIII. Drugs of Vegetable Origin,
XIV. Drugs of Animal Origin.

100. Volume of imported essential Basic Drugs in 1960 was Rs. 967.17 lakhs, as per details below:

Cost of Imported Essential Basic Drugs in 1960

		(Lakhs)		
A.	Sulpha Drugs	126·25		
	Anti-Tubercular I.N.H.	0·47		
	Anti-malarials	0·54		
	Vitamins and Preparations	130·96		
	Other Drugs and Pharmaceuticals ..	414·75	672·97	Lakhs.
B.	Antibiotics—			
	Aureomycin	28·82		
	Chloromycetin	57·59		
	Penicillin and its Preparations	36·68		
	Streptomycin and its Preparations ..	73·17		
	Terramycin	33·83		
	Other Antibiotics	64·11	294·20	Lakhs.
			967·17	Lakhs
			(Or 9·67	Crores).

101. List of Essential Basic Drugs required for Pharmaceutical Manufacture: Their Estimated Production in India and Quantity Required to be Imported, and the Essential Basic Raw Materials Required for Indigenous Manufacture of such Basic Drugs are given below:—

Name of the Drug.	Required quantity (Estimated Third Plan ending 1965-66).	Unit.	Production in India.	Quantity required to be imported.	Name of the basic raw materials required for indigenous manufacture.	Remarks.
A. SYNTHETIC DRUGS AND CHEMICALS:						
Sulpha Drugs						
Sulphathiazole and Sulphadiazine		Tonne ..	..	..	....	To consult the list of raw materials.
Sulphathiazole, Sulphadiazine		Do. ..	..	..	....	
Sulpha Pyridine and Sulphadimidine		Do. ..	..	..		
Sulphasomidine		Do ..			....	
Sulphadimidine		Do ..	..	..	....	
Sulphaguanidine	..	..	..	..	....	
Sulphacetamide Sodium	1,000	Do. ..	196·34	803·66	....	
Sulphanilamide						
Succinyl Sulphathiazole and Phthalyl Sulphathiazole.	..	Do. ..	..	..		
Sulphacetamide	..	Do. ..	..	..	Sulphanilamide	
Acetazolamide	..	Do. ..	..	..		
Anti-Tubercular Drugs						
P. A. S. and Salts	400	Do. ..	150·77	249·23	m-Aminophenol	
Isonicotinic Acid Hydrazide ..	100	Do. ..	58·98	41·02	G-picoline and Hydrazine Hydrate.	

Anti-Dysenery Drugs							
Iodochloro and Diiodoxy-Quinoline ..	75	Do. ..	44·64	30·46	Phenol, Cholorine and Iodine 8-Hydroxy quinoline, Chlorine and Iodine.		
Anti-Leprotic Drugs							
DDS and derivatives	40	Do.	14·3	26·00	Nitro-Benzene and Chlorosulphonic Acid P-nitrochloro-benzene and Potassium Xanthate.		
Synthetic Anti-Malariale							
Chloroquin and Amodiaquin ..	—	Do. ..	?	?	m-Chloraniline and Diethyl ethoxy-malonate 4-diamine 4 : 7-Dichloro-quinoline and derivatives.		
Anaesthetics							
Procaine Hydrochlor	75	Do. ..	5·24	69·76	Diethyl Aminoethyl and Benzocaine.		
Xylocaine	—	Kg ..	..	..	Diethylamine m-Xylindine.		
Analgesics Antipyretics						To consult the list of raw materials.	
Aspirin	800	Tonne ..	297·5	502·50	Phenol, Acetic Anhydride, Salicylic Acid.		
Phenobarbitone	20	Do. ..	Nil	20·00			
Phenacetin	200	Do. ..	16·55	183·45	P-phenetidine		
Amidoprine	?	Do. ..	Nil ..	Full.			
Metamizol	?	Tonne ..	Nil	Full	....		
Calcium Gluconate and other Calcium salts.	?	Do.	105·5	..	Glucose.		
Ferrous Gluconate	?	Do. ..	20·84	Nil	Glucose.		
Piperazine Salts	?	Do. ..	..	..			
Diethyl Carbamezine (Ditrazine).	?	Do. ..	3·29	..			

Name of the Drug.	Required quantity (Estimated Third Plan ending 1965-66).	Unit.	Production in India.	Quantity required to be imported.	Name of the basic raw materials required for indigenous manufacture.	Remarks.
Nikethamide	12	Tonne.	6·62	6·38	Nicotinic Acid. ..	
Oral Antidiabetics : Tolbutamide ..	10	Do. ..	2·15	7·85	Para-toluene Sulphonyl methyl urethane and Para toluene Sulphonamide.	
Chlorpropamide	?	Do. ..	..	..		
Meprobemate	?	Do. ..	2·26	?	Para-chlorbenzene Sulphonamide Propanediol.	
Antihistamines : .. .. .. (Meclozine, Buclizine, Cyclizine, Mepyramine maleate promethazine).	?	Do. ..	0·13	?		
Glycerophosphates	?	Do. ..	9·82	?		
B. SYNTHETIC HORMONES ..	?	Kg ..	340	?	Dioggenine from Dioscorea, Hecogenin from Sisal.	To consult the list of raw materials.
C. DURGS OF VEGETABLE ORIGIN :						
Emetine		Kg	259·8	?	Ipecac Root.	
Opium Alkaloids		Do.	2307	Nil	Opium.	
Glycosides of Digitalis	100	Do.	Nil	100	Digitalis lanata and Purpurea	
Ergot Alkaloids	50	Do.	Nil	50	Ergot of rye.	
Atropine Sulphate	50	Do.	Nil	50	Atropa Belladona.	
Scopolamine	10	Do.	Nil	10	Hyoscyamus Muticus.	
Reserpine	200	Do.	1·7	198·30	Rauwolfia Serpentina.	
Caffeine	100	Tonne	6·74	93·26	Tea wastes and prunings.	

Papain	10	Do.	Nil	10	Papaya fruit.	
Santonin	?	Do.	0·33	Major part.	Artemisia.	
Strychnine and Brucine	?	Do.	16·17	Nil (?)	Nux Vomica seeds.	
Quinine	?	Do.	34·3	Nil	Cinchona.	
D. VITAMINS						
Vitamin A	20	M.M.U.	17·57	2·43	Lemongrass oil/-ionone.	
Vitamin B1	70	Tonne	Nil	70		
Vitamin B2	10	Do.	Nil	10		
Vitamin B6	2500	Kg	141·1	2358·90	Kethoxy Pyridoxine.	
Vitamin B12	25	Do.	17·68	7·32	By fermentation.	
Folic Acid	?	Do.	Nil	Full		
Vitamin C.	125	Tonne ..	32·45	92·55	Glucose.	To consult the list of raw materials.
Nicotinic Acid, and amide	75	Do.	58·98	16·02	B-picoline.	
Vitamin P. (Catechite).	1·0	Do.	1·0	Nil	By-product in the production of Caffeine (from Tea Waste).	
E. ANTIBIOTICS :						
Penicillin	120	M.M.U.	62·38	57·62	..	
Streptomycin and Dihydro-streptomycin	150	Tonne	Nil	150·00	..	
Chloramphenicol	50	Do	6·02	43·98	p-nitro-acetophenone or cinnamic alcohol.	
Tetracyclins (including Chlortetracyclin DMCT and Oxytetracyclin)	50	Do.	11·53	38·47		
Nystatin	?	Do.	Nil	?		
Hamycin	?	Kg	Nil	?	..	Manufacture by Hindustan Antibiotics.
Other, like Neomycin, Bacitracin, Erethromycine.						

Name of the Drug.	Required quantity (Estimated Third Plan ending 1965-66).	Unit.	Production in India.	Quantity required to be imported.	Name of the basic raw materials required for indigenous manufacture.	Remarks.
F. ENDOCRINES:						
Insulin	1000	M.U.		Data not available	..	To consult the list of raw materials.
Pituitrin	30	Kg	?	Do.	..	
Cortisone Derivatives	500	Kg	?	Do.		
Adrenaline	50	Kg	?	Do.		
Pepsin	10	Kg	?	Do,		
Pancriatin						
A.C.T.H.	4	M.U.	?	Ditto.		
G. OTHER DRUGS:						
Citric Aicd	?	..	Nil	Full quantity.		
Salicylic Acid including Salicylates ..	1500	Tonne	?	?		
Benzoic Acid	?	..	?	?		
Pethidine HCL	?	Tonne	?	?		
Chlorbutol	?	Do.	?	?		
Preservatives Line						
Methyl Para Amino Benzoate, Cresol, Butyl Alcohol, Propyl Alcohol.	?	Tonne		Full quantity.		

102. List of Raw Materials for manufacture of essential basic drugs required in Pharmaceutical Industry:—

Name of Raw Material required for manufacture of Essential Basic Drugs.	Name of the Basic Essential Drugs for which the Raw Materials are required.	timated Annual irements.	Whether Imported or Indigenous.
1		3	4
Acetanilide	Sulphas ..	1,800	Imported.
Acetic Anhydride ..	.. ..	1,000	Do.
	Sulphacetamide	51	Do.
	Aspirin ..	800	Do.
	Phenacetin ..	144	Do.
	Acetazolamide ..	..	Do.
Acetylacetone	Sulphadimidine	180	Do.
Acetyle Chloride ..	Vitamin A ..	7	Do.
Acetoaceticester ..	Pyramidon Metamizolum (Novalgin).	100	Do.
4-Amino-2-Diethylamine methul phenol.	Amodiaquine ..		
M-Aminophenol	P.A.S. ..	380	Do.
O-Aminophenol	Di-iodo-hydroxy quinoline	11	Do.
Aluminium Isopropoxide ..	Chloramphenicol ..	200	Do.
N-Butylamine	Tolbutamide ..	20	Do.
M-Chloroaniline	Amodiaquine Chlorthiazide	45	Do.
Chlorobenzene	D.D.S. ..	40	Do.
P-Chloronitrobenzene ..	Phenacetin ..	275	Do.
Chlorsulphonic Acid ..	Sulphas Chlorthiazide	7,200	Do.
Cyanmethin	Sulphasomidine ..	26	Do.
Di-choloracetic acid ester ..	Chloramphenicol ..	32·5	Do.
2-Diethylamine ethanol ..	Procaine Hydrochloride	54	Do.
Diethylamino-1-methyl butylamine.	Chlorquine ..	14	Do.
Diethulamine	Nikethamide ..	13	Do.
Diethul ethoxy-methyleno maleate.	Chloroquine Amodiaquine ..	70	Do.
Oxalic Acid	Phenobarbitone ..	20	Do.
Dimethul	Pyramidon ..	70	Do.
ulphate	Novalgin ..		
Methyl Sulphate ..	Ditrazino ..		
Ethyl Bromide	Vitamin A ..	26	Do.
Guanidine Salts	....	1,260	Do.
	Sulphadiazine ..	1,003	
	Sulphadimidine ..	170	
	Sulphaguanidine ..	84	
Hexamine	Chloramphenicol ..	150	Do.
Hydrazine hydrate ..	I. N. H. ..	50	Do.
Hydrobromic Acid ..	Vitamin A ..	9·5	Do.
Iodine	Antidysentery drugs	68	Do.
Keto Acetol	Vitamin A ..	8·8	Do.
Malic Acid	Sulphadiazine ..	1,156	Do.
Metal Lithium	Vitamin A ..	2·1	Do.

Name of Raw Material required for manufacture of Essential Basic Drugs.	Name of the Basic Essential Drugs for which the Raw Materials are required.	Estimated Annual Requirements.	Whether Imported or Indigenous.
1	2	3	4
Metal Sodium	Barbiturates Pyrimethamine ..	12	Imported.
Metal Magnesium ..	Vitamin A	2·7	Do.
Nitroacetophenone ..	Chloramphenicol	150	Do.
O-Nitrophenol	Di-iodi-hydroxy-quinoline ..	7	Do.
P-Nitrotoluene	Procaine H.CL	73 63	Do.
Palmitoyl Chloride ..	....	25	Do.
	Chloramphenicol	15	Do.
	Vitamin A	10	
Phenol	....	1,000	Do.
	Salicylic Acid	945	Do.
	Iodochlorhydroxy quinoline ..	56·5	Do.
Phenylacetamide ..	Penicillin	350	Do.
Hydrazine Sulphate ..	Acetazolamide	170	Do.
Phosgene	Ditrazine (Diethyl-carbamazine) Meprobamate.	160	Do.
Phosphorous Oxychloride ..	Sulphadiamine Chloroquine Amodiaquine.	165	Do.
Phthalic Anhydride ..	Phathalysulphathiazole ..	6	Do.
Phosphorous Pentoxide ..	Nikethamide	15	Do.
B-picoline or	Nicotinamide	57	Do.
Ethylmethyl-pyridine ..	Nikethamide	88	Do.
Methylethyl-pyridine ..	Vitamin A	1·6	Do.
Gamma Picoline ..	I. N. H.	110	Do.
Piperazine Hydrate ..	Ditrazine	40	Do.
	Piperazine Adipate ..		
Sodium Cyamide ..	Barbiturates	21	Do.
Propargyl Bromide ..	Vitamin A	10·8	Do.
Sodamide	Chlorpromazine Promazine ..	10	Do.
	Mepyramine Meleate ..	0·6	Do.
	Promethazine	0·2	Do.
Tartaric Acid	Chloramphenicol ..	90	Do.
Thionyl Chloride ..	Procaine HCL	100 62	Do.
Thiourea	Sulphathiazole Acetazolamide	140	Do.
p-Toluene Sulphonyl chloride	Tolbutamide	..	Do.
Trimethylamine HCL ..	Sulphasomidine	9	Do.
Vinyl Acetate	Sulphathiazole	151	Do.

103. Of these the following production was planned during the Third Five-Year Plan:—

	Project.	Production planned or licensed (tons).
Acetanilide	H.O.C. ..	2000
Acetic Anhydride	Private Sector ..	800-900
Acetyl-acetone	I.D.P.	170
Acetyl-Chloride	Private Sector ..	50
Acetoaceticester	I.D.P. ..	100
O-Aminophenol	H.O.C. ..	250
N-Butylamine	H.O.C. ..	70
M-Chloroaniline	H.O.C. ..	100
M-Chlorobenzene	H.O.C. ..	500
Diethylamine	I.D.P.	50
Hexamine	I.D.P.	10
Hydrazine Hydrate	I.D.P.	10
Phenol	H.O.C. ..	1500
Phenyacetamide	H.O.C. ..	66
Phthalic Anhydride	H.O.C. ..	3000
Piperazine Hydrate	I.D.P.	40

H.O.C.—Hindustan Organic Chemical (Government).

I.D.P.—Indian Drugs and Pharmaceutical Ltd. (Government undertaking).

104. The following Herbal Drugs were imported during April 1962—March 1963:—

Articles.	Countries from which imported.	Quantity (Kg.)	Value in Rs.
Cocoa powder	Netherlands, U.K. ..	6,483	13,191
Aniseed	China, Singapore ..	12,370	15,185
Cassia	China, Malaya, Singapore, Hongkong.	1,12,704	16,87,304
Cinnamon	Ceylon, Malaya, Singapore, U.K.	11,311	63,263
Cloves	Singapore, Malaya, Zanzibar ..	9,19,228	1,30,53,143
Cumin	Afghanistan, Pakistan ..	2,11,828	9,66,025
Nutmeg	Ceylon, Malaya, Singapore ..	59,982	7,25,816
Balsam of Peru	Netherlands, U. K. ..	120	1,949
Balsam of Tolu	Belgium, France, Germany W., Netherlands, U.K., U.S.A.	4,401	78,566
Balsam of Copaiba ..	U.K., U.S.A. ..	544	7,979

Articles.	Countries from which imported.	Quantity Kg.	Value in Rs.
Gum Acacia ..	Australia, U. K. ..	8,131	33,357
Storax ..	France, U.K., U.S.A.	3,053	85,936
Gum Arabic ..	Aden, Kenya, Singapore, Sudan, Tanganika, U. K.	24,06,090	42,43,790
Gum Asafeotida ..	Afghanistan, Iran, Pakistan W., U.K.	1,63,480	10,90,797
Gum Tragacanth	Germany W., Iran, U.K. ..	42,619	3,17,527
Gum Mastic ..	Japan	1,308	6,614
Gum Myrrh ..	Aden, Australia, Somalliland, Sudan, U.K., U.S.A.	14,340	59,158
Belladonnae leaves and roots	Belgium, Bulgaria, Rumania, U.K., Yugoslavia.	19,418	43,428
Cascara sagrada bark ..	U.K., U.S.A. ..	11,247	40,805
Cubebos	Fedn. Malaya, Singapore	70,228	2,49,925
Glycyrrhizae glabra dried Rhizome and Root.	Afghanistan, Iran, Pakistan, U.K.	3,68,577	3,82,519
Ipecac dried Rhizome and Roots	U.K., U.S.A. .. .	16,291	13,71,814
Sarsaparilla dried Roots ..	Belgium, Jamaica, U.K., U.S.A.	1,884	9,285
Agar Agar ..	China, Denmark, Hongkong, Italy, Japan, U.K., U.S.A.	15,326	2,76,183
Ext. Aloes	Aden, Rhodesia, U.K., U.S.A.	.	10,813
Ext. Belladonnae —	Germany W., U.K. ...	835	17,626
Ext. Cas, Sag — —	U.K. — — —	.	12,229
Ext. Glycyrrhizae ...	Italy, U.K., U.S.A. ..	.	19,614
Opium Crude	Australia, Italy, U.K., U.S.A.	17	1,242
Olive Oil crude, refined or purified.	France, Italy, Spain, U.K.	29,946	1,40,741

105. Progress in manufacture of some of these drugs in given below:—

Item.	State.	Starting raw materials.	Licensed. 31st December, 1962.		Installed capacity on 31st December, 1962.		Production 1962.	Unit.
1. Antibiotic.								
Penicillin	Maharashtra ..	Basic raw materials ..	....		45	65	62·38	M. M.U.
	Gujrat ..	Ditto	....		10			
	Bengal ..	Ditto	....		10			
	U. P. ..	Ditto	....		Nil			
Streptomycin and Di-hydrostreptomycin.	Maharashtra ..	Ditto	90	190·18	45	45	..	
	Gujrat ..	Ditto	15		Nil			
	Bengal ..	Ditto	0·18		Nil			
	U.P. ..	Ditto	85		Nil			
Chloramphenicol	Maharashtra ..	p-nitro-acetophenone or Cinnamic alcohol. ..	28·6	51·6	15		6·02	Tonne.
	Delhi ..	Ditto	5·0					
	Bengal ..	Ditto	18·0					
Tetracyclins (including Chlor-tetracyclin D.M.C.T. and Oxytetracyclin).	Maharashtra ..	Basic raw materials ..	1·5	139·5	Nil	15·0	11·53	Tonne.
	Gujrat ..	Ditto	13·0		10·0			
	Punjab ..	Ditto	5·0		5·0			
	U.P. ..	Ditto	120·0		Nil			
2. Sulpha.								
Sulphathiazole and Sulphadiazine ..	Gujrat ..	....	251		251		..	Tonne.
Sulphathiazole, Sulphadiazine, Sulphapyridine and Sulphadimidine.	Maharashtra ..	Basic raw materials ..	210		60		..	Tonne.

Item.	State.	Starting raw materials.	Licensed. 31st December, 1962.		Installed capacity on 31st December, 1962.		Production 1962.	Unit.
Sulphazomidine	Maharashtra ..	Basic raw materials	72	1091	72	399	196·34	Tonne.
Sulphadimidine	Andhra ..	Ditto	280		Nil		..	Tonne.
Sulphaguanidine	Andhra ..	Ditto	180		Nil		..	
Sulphacetamide, Sodium ..	Andhra ..	Ditto	50		Nil		..	
Sulphanilamide	Andhra ..	Ditto	50		Nil		..	
Succinyl Sulphathiazole and Pthalyl Sulphathiazole.	Maharashtra ..	Ditto	7		Nil		..	Tonne.
Sulphacetamide etc.	Bengal ..	Sulphanilamide	16		16		..	
Acetazolamide	Andhra ..	Basic raw materials ..	25		Nil		..	
3. Anti-Tubercular.								
P.A.S. and Salts	Maharashtra ..	m-aminophenol	380	516	60	196	150·77	Tonne.
	Andhra ..	Ditto	136		136			
Isonicotinic acid hydrazide (INH) ..	Gujrat ..	G-picoline and Hydrazine Hydrate	27·0	126·4	27·0	55·5	58·98	Tonne.
	Maharashtra ..	Ditto	16·9		15·6			
	West Bengal ..	Ditto	27·5		12·9			
	Andhra ..	Ditto	55·0		Nil			
4. Anti-Leprotic.								
D.D.S. and derivatives	Maharashtra ..	O-Nitrobenzene and Chloro sulphonic acid and p-nitro-chlorobenzene & potassium xanthate	11·0	40·5	11·0	18·5	14·3	Tonne.
	Bengal ..	Ditto	19·5		7·5			
	Andhra ..	Ditto	10·0		Nil			

Procaine H.cl	..	..	..	Maharashtra	..	Diethyl aminoethyl & Benzocaine Basic raw materials.	40	90	6	6	5·24	Tonne
				Gujrat	..	Ditto	50		Nil			
Vitamins												
Vitamin A	..	..		Maharashtra	..	Lemon grass oil/B-ionone ..	20		20		17·57	M.M.U.
Vitamin B_1	..	..		Andhra	..	Basic raw materials ..	30		Nil		Nil	Tonne.
Vitamin B_2	..	..		Andhra	..	Ditto	5		Nil		Nil	Tonne.
Vitamin B_6	..	..		Gujrat	..	Methoxy pyridoxine Ry fermentation.	1000		500		141·1	Kg.
Vitamin B_{12}	..	..		Maharashtra	..	Ditto	25	37	10	10	17·68	Kg.
				Gujrat	..	Ditto	12		Nil			
Folic Acid	..	..		Andhra	..	Basic	1,000 Kg.		Nil		Nil	
Vitamin C	..	..		Gujrat	..	Glucose .. .	60		50			
Other Drugs				Maharashtra	..	Ditto	Nil		Nil		Nil	
Emetine		..		Bengal	..	Ipecac root	440	590 Kg.	440	440	259·8	Kg.
				Maharashtra	..	Ditto	150		Nil			
Opium alkaloids	..	..		U.P.	..	Opium	2,000 Kg.		2,200		2,307	Kg.
Glycosides of digitalis		..		Kerala	..	Digitalis lanata & purpurea ..	100 Kg.		Nil		Nil	Kg.
Ergot alkaloids	..	..		Kerala	..	Ergot of rye	50		Nil		Nil	Kg.
Atropine Sulphate	..	..		Kerala	..	Atropa Belladonna ..	50		Nil		Nil	Kg.
Scopolamine	..	..		Kerala	..	Hyoscinus	10		Nil		Nil	Kg.
Reserpine	..	..		Maharashtra	..	Rauwolfia Serpentina ..	12	212	12	12	1·7	Kg.
				Kerala	..	Ditto	200		Nil			

Item.	State.	Starting raw materials.	Licensed. 31st December, 1962.		Installed capacity on 31st December, 1962.		Production 1962.	Unit.
Caffeine	Bengal	Tea waste and prunnings	10	73	5·8	8·8	6·74	Kg.
	Punjab	Ditto	3		3			
	Kerala	Ditto	60		Nil			
Vitamin P (Catechite)	Kerala	By-product in the production of caffeine.	1·0		Nil		Nil	
Papain	Kerala	Papaya fruit	10		Nil		Nil	
Santonine	Punjab	Artemisia	1·2	2·2	1·2	2·2	0·35	
	Kashmir	Ditto	1·0		1·0			
Strychnine and Brucine	Andhra	Nux Vomica seeds	9·0	36	9·0	36	16·17	
	Punjab	Ditto	12·0		12·0			
	Bengal	Ditto	15·0		15·0			
Aspirin	Maharashtra	Phenol & Acetic anhydride	660	760				
	Bengal	Salicylic acid and Acetic anhydrous.	100		196		297·5	
Phenobarbitone	Andhra	Basic raw materials	10		Nil		Nil	
Phenacetin	Andhra	Basic raw materials p-phenetidine.	100	132	Nil	22	16·55	
	Maharashtra	Ditto	20		20			
	Bengal	Ditto	12		2			
Amidopyrin	Andhra	Basic raw materials	40		Nil		Nil	
Metamizol	Andhra	Basic raw mateirals	10		Nil		Nil	

Calcium Gluconate & other Calcium salts.	Maharashtra	..	Glucose	..	..	143·7	100		
	Gujrat	..	Ditto	..	..	96	247·7 Tonne.	Nil	108	105·5	Tonne.
	Bengal	..	Ditto	..	..	8		8	
Ferrous Gluconate	Gujrat	..	Glucose	..	..	12		8·5	
	Maharashtra	..	Ditto	..	..	35·2	48·2 Tonne.	20·2	29·7	20·84	Tonne.
	Bengal	..	Ditto	..	..	1·0		1·0	
Piperazine salts	Andhra	..	Basic raw materials		..	50		Nil		..	
Diethyl Carbamazine (Ditrazine) ..	Maharashtra	..	Basic raw materials		..	20·66		20·66	
	Andhra	..	Ditto	..	..	30·00	50·66 Tonne.	Nil	20·66	3·29	Tonne.
Nikethamide	Gujrat	..	Nicotinic acid	..	..	4·8		4·8	
	Bengal	..	Ditto	..	..	2·3	7·1 Tonne.	2·3	7·1	6·62	Tonne.
Oral antidiabetics Tolbutamide ..	Maharashtra	..	paratoluene sulphonyluene sulphonamide.			39·0		39·0	
	Bengal	..	Ditto	..	..	3·0	44·5 Tons.	Nil	39·0	2·15	Tonne
	Andhra	..	Ditto	..	..	1·0		..	
Chlorpropamide	Punjab	..	para-chlorobenzene sulphonamide.			1·5 Tons.		..		..	
Meprobamate	Maharashtra	..	Propanediol	..	..	1·8 tons.		10·8		2·26	Tonne.
Antihistamines Meclozine, Buclizine, Mepyramine, Maleate, Promethazine. (Etc.).	Maharashtra		Basic raw materials			5·95 tons.		5·95		0·13	
Glycerophosphates	Andhra		Basic raw materials			54		54	
	Maharashtra		Ditto			10	64 tons.	..	54	9·82	Tonne.
Insulin ..	Maharashtra		Basic raw materials			1500 MU		..		..	MU

106. Hormones can be extracted from vegetable kingdom also. For instance, Hecogenin can be recovered from Sisal (Agave Sisalana) from which Cortizone can be manufactured. Although West Bengal Government have a 1200-acre Sisal plantation in Rajnagar in Birbhum district, no attempt has been made to recover Hecogenin.

107. The only unit which produces Hormone from this source is located in Maharashtra and against their licensed capacity of 6458 Kg. they have installed only 458 Kg. and produced 340 Kg.

108. A list of medicinal plants under cultivation in West Bengal is given below :—

List of Medicinal Plants under Cultivation at Rongo.

1. Acorus calamus.
2. Ammi majus.
3. Atropa acuminata.
4. Atropa belladonna.
5. Digitalis purpurea.
6. Digitalis lanata.
7. Datura Stramonium.
8. Hyoscyamus niger.
9. Lemon grass (Cymberogon citratus).
10. Mentha piperita.
11. Mentha arvensis.
12. Ocimum kilimandcharicum.
13. Ocimum basilicum.
14. Papaver Somniferum.
15. Rauvolfia serpentina.
16. Rauvolfia canescens.
17. Rauvolfia densiflora.

MISCELLANEOUS

1. Asparagus maritimus.
2. Cassia auriculata.
3. Dioscorea species.
4. Grewia populifolia.
5. Maranta arundinacea.
6. Pyrethyum.

FOREIGN SPECIES

(Received from the Union of Soviet Socialist Republic, Russia)

1. Atropa belladonna.
2. Calendula officinalis.
3. Digitalis ambigua.
4. Euphorbia latyris.
5. Echium rubruum.
6. Echinacia purpurea.
7. Papaver somniferum.
8. Polemonium coerubum.
9. Pheum rhaponticum.
10. Rhaponticum carthamoides.
11. Pyrethrum.
12. Senecis platyphyllus.
13. Adonis vernalis.
14. Ammi majus.
15. Anisodus luridus.
16. Ammi visnaga.
17. Chenopodium anthelminticum.
18. Chenopodium ambrosoides.
19. Convallaria majalis.
20. Datura innoxia.
21. Delphinium elatum.
22. Ephedra equisetina.
23. Erysimum. canescens
24. Leonurus cardiaca.
25. Panax ginsong.
26. Solanum aviculare.
27. Senecio platyphyllus.
28. Thermopsis lanceolata.
29. Veretrum lobelianum.
30. Saccurinaga sub-fruticosa.
31. Succors of Mentha Piperita.-(500).

Seeds received from United Kingdom.

1. Lunaria aurua L.
2. Lunaria aurua-alba.
3. Engelica archangelica.

Seeds received from Kew Gardens, England.

1. Digitalis lanata.
2. Digitalis ferruginea.
3. Digitalis lutea.
4. Digitalis parviflora.
5. Digitalis ambigua.
6. Digitalis mutonensis.
7. Digitalis purpurea.
8. Digitalis purpurea, Wild in Surrey, England.
9. Digitalis purpurea—Garden strain.

Seeds received from France.

1. Digitalis lanata.
2. Digitalis purpurea.
3. Atropa belladonna.
4. Hyoscyamus niger.
5. Lavandula officinalis.
6. Mentha pulegium.

Total 69 Species of Medicinal Plants are being cultivated at Rongo.

109. Attempts are being made to develop foreign species and the Commission have noted with satisfaction that Russian, French and British species are being grown on experimental basis. They hope that in course of time Bengal will be able to produce the requirements for the whole of India and also develop a profitable export market.

110. Regarding drugs of animal origin, the Commission would recommend to the Government of West Bengal immediate investigation into the condition of slaughter houses for conserving valuable hormone and glandular products for sale to the licensed manufacturers. At present there is considerable shortage in this. For instance, Adrenaline and Corticosteroids are not produced in this country as the necessary apparatus and trained personnel are not easily available so far. Government may also consider the manufacture of synthetic preparation of these hormones. Insulin and Heparin are wholly imported.

111. Details of essential drugs production and comments on raw materials are given below:

I. Antibiotics

LIST OF MICRO-ORGANISMS FOR PRODUCTION OF ANTIBIOTICS OF COMMERCIAL IMPORTANCE

The following micro-organisms are needed for production of antibiotics:

Name of the Antibiotics.	Name of the Strains of micro-organisms.
1. Streptomycin	.. Streptomeces griseus (or by any other means)
2. Penicillin	.. Penicillin notatum.
3. Chloramphenicol	.. Streptomyces Venezuelae (or by synthetic method).
4. Chlortetracyclin (Aureomycin)	.. Streptomyces Aureofaciens.
5. Oxytetracyclin	.. Streptomyses Nimosus.
6. Tetracyclin	.. By the catalytic reduction of Chlortetracyclin or Oxytotracyclin.
7. Neomycin	.. Streptomyces frediae.
8. Bacitracin	.. Bacillus lichemiformia and Becillus subtilisvar.
9. Haymycin	.. Produced by Hindusthan Antibiotics by own method.

THE STRAINS OF MICRO-ORGANISMS FOR ASSAY OF ANTIBIOTICS OF COMMERCIAL IMPORTANCE ARE:

1.	Streptomycin	Bacillus Subtillis (B.P.). Klebsiella pneumoniae (U.S.P.).
2.	Penicillin	Bacillus sabtillis (B.P.) Staphylococcous Aureous (U.S.P.)
3.	Chloramphenicol	Sercinalutea (U.S.P.)
4.	Tetracyclin	Becillus pumilus (B.P.) Stephyolcocous aurous (U.S.P.)
5.	Neomycin	Bacillus pumilus (B.P.) Staphylococous aureus (U.S.P.)
6.	Bacitracin	Micrococous Flavus (B.P.) Micrococous Flavus (U.S.P.).
7.	Aureomycin or Chlortetracyclin	Bacillus pumilus (B.P.)

(1) Penicillin

The pilot plant started operation at Pimpri factory of Hindustan Antibiotics in March, 1955. Alembic Chemical Works Co. Ltd., and Standard Pharmaceuticals Ltd., with capacity of 4.8 MMU and 1.8 MMU, were commissioned. All have gone into production. During the Third Plan, another antibiotic factory is to be set up at Rishikesh with a capacity of 140 MMU. Alembic is to expand its capacity to 20 MMU. The total installed capacity would thus come to 215 MMU. At 3 MMU per capita per annum, the requirement would be 180 MMU, leaving an exportable surplus.

There is shortage today and licences for importing bulk is issued to manufacturers. This should be stopped. The existing licensing capacity should be fully exploited. Representatives of Messrs. Standard Pharmaceuticals Ltd., while deposing before the Commission, stated that they can step up their production but Government would not allow them to do so. Such attitude is not helpful.

(2) Chloramphenicol

The total licensed capacity is 51.5 tons. Of this, the installed capacity is 15 and production is 6.02 tons. The basic raw materials are—cinnamyl alcohol or p-nitro-acetophenone. Both these have to be imported. Boehringer Knoll (1) Ltd., commenced production in 1962 from imported intermediate. They are now installing equipment for production from benzaldehyde. In West Bengal, Dey's Medical Stores P. Ltd., have a licence for 18 tons per annum. They have now gone into experimental production.

(3) Streptomycin

This effective anti-tubercular antibiotic is of vital interest to India. According to the Development Council, demand at the end of Second Plan stood at 18,000 Kg. In 1959 Government approved manufacture of 45,000 Kg. of Streptomycin and Di-Hydrostreptomycin by Hindustan Antibiotics in collaboration with Merck Sharp Dohme of the U.S.A. The plant was commissioned recently. Trial operations have commenced.

In Bengal, Standard Pharmaceuticals Ltd. have a licence for 1.8 tons per annum. In Gujerat, Sarabhai Chemicals have a licence for 15 tons per annum. It is understood that during the Third Plan, an 85 tons unit will be set up in the public sector at Rishikesh. At present imports are through a Government approved agency for distribution among actual users. Production and quantity imported are given in the table in the appendix.*

* Appendix has not been printed.

(4) Tetracycline

Production of this was started by Atul Products Ltd., of Bombay in collaboration with Cyanamid Ltd., of U.S.A. Tetracyclin is produced from Chlortetracyclin.

II. Sulpha Drugs

Excepting Sulphacetamide, which is manufactured from sulphonamide, all other sulpha drugs are manufactured either by private firms on the West Coast in collaboration with foreign manufacturers or at the Indian Drugs and Pharmaceuticals plant in Andhra. Production during 1962 was 196.34 tons against the installed capacity of 399 tons and licensed capacity of 1,091 tons. In West Bengal, however, the licensed capacity is 16 tons and there is no shortage of raw materials excepting alcohol.

III. Anti Tubercular Drugs

(1) P. A. S.

Manufacture of P.A.S. and its salts was first started in India by Nivea Products. After some time they stopped production. Thereafter Biochemicals and Synthetic Products Ltd., of Sanatnagar, Andhra, commenced production in 1956 Pfizer P. Ltd. started production in 1962. All of them based their production on meta-amino-phenol. Production during 1962 was 150.77 tons against licensed capacity of 560 tons. It is to the credit of Bengal manufacturers that East India Pharmaceutical Works Ltd., and G. D. A. Chemicals Ltd., of Calcutta have made considerable progress in research for production of P.A.S. acid from raw materials of indigenous sources. None of them have gone into commercial production. They require encouragement and financial assistance for their efforts.

(2) I. N. H.

This is being manufactured on a fairly large scale. The total licenced capacity is 126.4 tons, installed capacity 55.5 tons, and production is 58.98 tons. This shows that production can definitely exceed the rated installed capacity. In West Bengal total installed capacity is 12.9 and licensed capacity 27.5 tons. Manufacture is from Gamma Picoline and Hydrozine Hydrate. Attempts are being made for producing it from picoline cuts and urea.

IV. Antileprotic Drugs

Till 1954 only Bengal Chemical & Pharmaceutical Works Ltd., and Bengal Immunity Company Ltd., of Calcutta were manufacturing antileprotic drugs with technical processes developed by them, based on basic raw materials. The combined capacity was 2,920 Kg., of which B.C.P.W. Ltd. was manufacturing 2,720 Kg. Albert David Ltd. of Calcutta also started production with a capacity of 500 Kg. The total installed capacity is 18.5 tons against licensed capacity of 40.5 tons. Production is satisfactory, viz. 14.3 tons. There does not appear to be any shortage of raw material. The present system of issuing licence for import in bulk for the Anti-Leprosy Scheme has caused hardship to the indigenous manufacturers. Another anti-leprosy drug, Thiacetazone, has been manufactured by B.C.P.W. Ltd., B. I. Ltd., and Unichem Laboratories. This is said to be effective against Tuberculosis also.

V. Anti Dysentery Drugs

Iodo-chloro and Di-iodo-hydroxy-quinoline are anti-dysentery drugs of choice. The total licensed capacity is 77.9 tons and installed capacity is the same. Production is 44.54 tons per annum. They are mostly manufactured from Phenol, Chlorine and Iodine, while some produce it from 8:hydroxyquinoline, chlorine and iodine.

VI. Anti Malarial Drugs

The production of Quinine and its derivatives is adequate. The commission would, however, recommend manufacture of Chloroquin and daraprim. At present, 30,000 lbs. each of Paludrine and Chloroquin are being produced.

VII. Anaesthetics

The demand for different groups of anaesthetics are:—

Ether	720 tons.
Chloral Hydrate	60 tons.
Ethyl Chloride	38 tons.
Chloroform	75 tons.
Procaine Hydrochloride	50 tons.

Production of choloroform had been given up, being uneconomic. Production of procaine hydrochloride has been licensed in Maharashtra and Gujarat from diethylaminoethenol and- Benzocaine. As against licensed capacity of 90 tons, installed capacity is only 6 tons. As this is not manufactured in West Bengal the Commission do not make any recommendation, but would invite the attention of Government to the manufacture of Xylocaine from di-ethyla-mino-methyl-Xidine, for which a 500 Kg. unit has been licensed in Gujerat but nothing has been done so far.

VII. Anti Diabetic Drugs

Albert David Ltd. have already installed a 3-ton unit for manufacture of Carbutamids and Tolbutamide. They have licence for manufacture of chlorpropamide. Bengal Chemical have started production of Chlorpropamide by a process developed and patented by them from indigenous raw material. Bengal Immunity also have a licence for manufacture of 1 ton of Beta-phenylethyl Biguanide for which they have developed a technique themselves. Small scale production has been started.

IX. Analgestics, Anti Pyretics, etc.

Aspirin is manufactured from phenol and acetic anhydride, of which Martin & Harris Ltd. of Calcutta have a licence for 100 tons, Sodium Salicylate is produced by Calcutta Chemical Co. Ltd., who have installed capacity of 12 tons. They also produce 12 tons of Phenacetin. They have been granted an expansion licence for 12 tons per annum. Licence has also been issued for Amidopyrine and Metamisol to be produced from basic raw materials by Indian Drugs & Pharmaceuticals in Andhra.

X. Anthelminthic Drugs

The only unit producing Piperazine Adipate is British Drug Houses (I.) Pvt. Ltd. of Bombay. They manufacture it from imported intermediates.

XI. Vitamins

All the vitamins are produced in Gujerat and Maharashtra. As no firms produce this in West Bengal, the Commission have not considered the question of raw materials for these.

XII. Hormones

Adrenaline is recovered from glands of animals, but because of the backwardness of slaughter houses there is no manufacture in this country. Adrenaline can also be produced synthetically. The entire licensed capacity is in Maharashtra, totalling 2,468 Kg., of which installed capacity is 458 Kg. and production during 1962 was 340 Kg.

XIII. Drugs of Vegetable Origin

(1) Emetine

For this Bengal has licensed capacity of 440 Kg., installed capacity is 440 Kg., and production in 1962 was 259.8 Kg. Emetine is derived from Ipecac Root and there is no shortage. Maharashtra was given licence for 150 Kg., but they have not started so far.

(2) Strychnine and Brucine

In recent years there has been a shortage of Nux Vomica seeds, due to unrestricted export. Reduced demand for Brucine, which is used for denaturing alcohol, is causing anxiety to the Indian producers. Government of West Bengal are, however, allowing denaturing industrial alcohol by Brucine for special purposes, and it is expected that difficulty caused by fall in market demand will be greatly resolved by this.

(3) Reserpin

This is derived from Raulwolfia Serpentina. Against the total licensed capacity of 212 Kg., installed capacity is 12 Kg., and actual production is 1.7 Kg.

(4) Caffeine

In Bengal, licensed capacity for Caffeine is 10 tons, installed capacity is 5.5 tons. This is derived from tea wastes and prunnings, of which there is no shortage. In fact there is a lot of wastage of raw materials. The high rate of 'freight' on tea-waste has greatly handicapped the industry, as railway authorities charge the same rate for tea-waste as for tea. It is expected that with the opening of broad-guage line to North Bengal and establishment of Phytochemical Factory near Siliguri, which has been recommended by the Commission, production of Caffeine will go up considerably and we will be able to export instead of importing.

(5) Ephedrine and Santionine

These are not produced in West Bengal, so the Commission did not consider the question of raw materials or plant for these.

XIV. Drugs of Animal Origin

As already pointed out, many hormones including Insulin, Heparin, etc. are not produced from basic raw materials. Various types of Sera are being produced by several concerns in West Bengal. There is no complaint of any shortage of raw materials or plant, equipment, etc.

Miscellaneous Drugs

(1) Calcium Gluconate

This and other calcium salts are manufactured in India. Licensed capacity in Bengal is 8 tons and installed capacity is the same. There is no shortage. Calcutta Chemical Co. have proposed manufacture of Lactic Acid for internal consumption and export. This would help manufacture of

Calcium Lactate. Tariff protection was discontinued from the end of 1960 as the Tariff Commission noted that indigenous industry had an advantage of nearly 8 per cent. on the foreign competitors against landed cost.

(2) Saccharin

This was originally produced from imported orthotoluene sulphonamide. Sarabhai Chemicals have started production from phthalic anhydride. There is no shortage. Installed capacity of Calcutta Chemical is 6 tons.

112. There has been some progress in the manufacture of synthetics in this country, but many have to be imported. It is necessary that production of synthetics should be developed. Development Council has assessed the requirement of important raw materials. These are given in Appendix in Part II of the Report.*

113. Raw materials for industries are under Entry 28 of the Indian Customs Tariff Schedule and, therefore, subject to high rate of duty. Raw materials of animal origin are not readily available from local sources because of the condition of slaughter houses. Unavailability of these materials and their high price have affected the industry. Scientific abattoirs with cold storage should be started in West Bengal without delay. It is stated that poor quality of the animal stock is one of the reasons for postponing the proposal for a Central Glandular Products Plant even with foreign collaboration. The Commission is unable to accept this argument. Insulin, ACTH, Pituitrin, Adrenaline, medical pepsin can definitely be recovered if slaughter houses are modernised in cities like Calcutta.

114. For economic production of endocrine products, raw materials from various slaughter houses should be collected.

115. In Calcutta 5 slaughter houses, including 3 big ones, slaughter 228,000 sheep and goat, 6,000 buffalo and bullock and 19,000 pig per year. The Russian experts who visited this country in October, 1956, led by Dr. A. G. Netradze, were of the opinion that it would be possible to collect endocrine products per year. Pancreas (from sheep and goat) 659,000 Kg. This would yield 39 million units of Insulin. Buffaloes, bulls, and pigs would similarly yield 16,900 Kg. of glandular raw materials which would yield 21 million units of Insulin.

Similarly, Hyprophysis from sheep, goat, buffalo, bull and pig would yield 12 million units of ACTH powder. Slimy membranes of pig stomach would yield 4,600 million units of medical Pepsin.

Of course this will mean that there should be:

(1) Cold Storage (Deep Freeze) for raw materials;

(2) Preparation of intermediate products;

(3) Manufacture of final products, including bottling of human blood substitute.

Glandular materials have to be collected in temperature not exceeding —40C, in special containers for production, the following equipment will be needed:

(1) Glass-lined steel reactors of 100 to 500 litres capacity for extraction, hydrolysis, precipitation and sterilising;

* Part II of the report has not been printed.

(2) Measuring and storage vessels and distillation stills of stainless steel;

(3) Vacuum stills;

(4) Vacuum pumps;

(5) Settling centrifuges;

(6) Heaters and sterilizers;

(7) Quick freezing equipment;

(8) Hypophysis cutters;

Sulphuric acid, Hydrochloric acid, Caustic soda, Ammonium sulphate, Ethyl alcohol, Acetic and Oxalic acids, Ethyl ether, ionex change resin and dry ice. Most of these are available in India.

116. The Commission have specially considered the question of shortage of Alcohol. It is an important raw material for some of the essential drugs like Nicotinamide, Luminal, Chloral Hydrate, Ether, Ethyl Chloride, I.N.H., Chlorbutanol and D.D.T.

117. Ethyl alcohol was produced on large scale during the second world war to supplement gasoline. The demand for power and industrial alcohol rose to 30 million gallons in 1960-61. It was estimated that nearly 1 million tons of molasses from 2.3 million tons of sugar would be adequate for 45 million gallons of alcohol. Further 1/2 million gallons of alcohol could be produced from Mahua (Basis Letifolia). The distilling capacity of 53 distilleries is mainly in Uttar Pradesh, Andhra and Maharashtra with 22 million, 4.2 million and 4.2 million gallons, respectively. West Bengal, with 3 distilleries, has an annual capacity of 1.5 million gallons. Petro-chemical Committee have estimated the requirement of alcohol at 75,60,000 gallons for drugs, liquors and denatured spirit during 1955-56. The demand for alcohol in West Bengal from industries is 21,500 gallons of which more than 15,000 gallons go for non-drug industries.

The Commission noted with concern that the recommendations of the Pharmaceutical Enquiry Committee (1953) have not been implemented by the State Governments. At page 95 of the Report the Committee stated:

> "We feel that some of the restrictions imposed by the States where prohibition exists are likely to interfere in the progress of this industry. For example in the State of Bombay in the interest of prohibition, production of rectified spirit has been made a State monopoly and its import from other countries has been prohibited. The pharmaceutical firms in the State which have their own distilleries are not allowed to make rectified spirit for sale to other pharmaceutical manufacturers, but have to be restricted to meet only their requirements. Distribution of molasses is controlled and its supplies being curtailed to these distilleries, although available in plenty, they are being forced to use sometimes a less suitable raw material like Mahua flowers. For the alcohol produced and used in these factories a heavy bond fee is charged. These factors increase the cost of production of alcohol and place the manufacturers at a disadvantage in the production of pharmaceuticals derived from alcohol when compared with other firms in the rest of the country. The position of pharmaceutical manufacturers who have no distilleries of their own is much worse as they have been compelled to buy rectified spirit from Government distilleries at an exorbitant high price, in addition to paying heavy fees for

transportation to their factory. The cost per gallon of rectified spirit in the State of Bombay is reported to be more than double the price at which it is available in other States. It is therefore, impossible for these pharmaceutical factories to undertake production of solvents and fine chemicals derived from alcohol although they have other facilities for undertaking such work."

119. The restriction placed by state excise authorities on movement of alcohol has aggravated the situation. It is true that free movement might result in leakage and alcohol findings its way to the black-market but in the interest of drug industry the risk has to be taken. The Pharmaceutical Enquiry Committee in paragraph 3.8 of their Report at Page 97 categorically stated that restriction imposed by Behar Government on the export of molasses has resulted in considerable hardship to the industry. The Committee recommended a better co-ordination between the two States.

120. Dependance on agricultural products for extraction of ethyl alcohol, of which there is a considerable shortage, would not be in the interest of the industry in the long run. The Commission is strongly of the opinion that availability of Alcohol at reasonable prices is a 'sine-qua-non' for the development of drug industry. In view of the reasons enumerated above the Commission strongly recommends that the State Government should immediately ensure, refining of molasses into Alcohol in adequate quantities in West Bengal.

121. Another possible alternative might be the starting of a Naptha Cracker in West Bengal. The surplus Naptha from Koyali or Barauni may be made available. In case surplus naptha is not available, cracking might start with crude oil. The butylene stream may be made available to the rubber industry propylene stream for synthetic fibre industry; and the ethylene stream being tapped for industrial alcohol.

122. The other important raw material necessary for the synthesis of sulpha drugs, P.A.S., anti-dysenteric drugs like Iodo-chloroxy-quinoline, analgesics like Aspirin, Sodium Salicylate, is Benzene. No shortage of Benzene was reported by the manufacturers. The principal installed capacity of nearly 5 million gallons is in the steel plants, of which Durgapur has a capacity of 2 million gallons. Benzene is utilised for synthetic phenol, and is used in large quantity for synthesis of styrene for polystyrene and co-polymer. Foam and high impact Resins, polystyrine fibres. It is also consumed for manufacture of D.D.T., Mallic Anhydride, Analene. It is expected that Benzene will also be available from petrochemical sources, from catelytically reformed gasoline and steam cracking of naptha for production of ethylene which yields benzene as byproduct. Therefore, even after meeting the demand from other Chemical industries, there should be ample supply for drug manufacture.

2.3. PLANTS AND MACHINERIES

123. The Commission met the representatives of some of the drug manufacturing concerns, for ascertaining their difficulties in the matter of procurement of plants; machinery and laboratory equipments. The list is given in the Appendix II*.

Shri Udayan Chatterjee, Additional Director of Industries, Government of West Bengal, and Dr. S. Roy, M.B., Ph.D. (Lond.), Superintendent of Calcutta Corporation Vaccine Institute were also present on invitation.

*Appendix II has not been printed.

124. The Commission learnt from the representatives that difference in prices of plants and equipment imported from sterling and rupee currency areas varied with the nature of the equipments.

Shri Udayan Chatterjee added that the performance of instruments of Japanese manufacture were satisfactory but the manufacturers were poorly represented in this country and therefore facilities for servicing were inadequate and availability of spares difficult. This was true of iron-curtain countries also as their trade policy is from State to State and on an 'ad-hoc' basis.

125. The consensus of opinion appeared to be that pharmaceutical machinery is undergoing rapid changes in design, and a machine of today will become obsolete in no time. For example, the Single Punch Tablet Making Machine was now out-moded by High Speed Multiple Punch Machine. Tablet making machines of indigenous manufacture were liable to vibration during operation and the size of tablets produced was not uniform for lack of balancing of the plant. The Commission felt that instruments for such specialised works should be imported for the time being, but the drug manufacturers should try to procure these machines from rupee currency countries, keeping in mind, other things being equal, the difficult foreign exchange position.

126. Most of the representatives stated that ampoule making by manual labour should be replaced by automatic ones. The Commission was concerned to learn that there was only one factory making glass for manufacture of ampoules in West Bengal, but these people were trying to shift part of their factory to Bombay.

The representatives stated that their proposal for making ampoules was turned down by the West Bengal Government in 1963 on the ground that there were already a large number of ampoule makers—but Bombay manufacturers were permitted to make these ampoules. West Bengal manufacturers had no choice in the matter of selection of proper quality of glass and, therefore, in the course of production they had to use glass without test.

127. In view of the highly specialised nature of synthetics in which a delicate pH balance has to be maintained, the Commission recommends that quality of glass should receive due attention and tested neutral glass should only be used for manufacture of parenterals.

128. The Commission would strongly recommend that permission be granted by the West Bengal Government to the manufacturers for such plants for production of glass ampoules.

129. The Commission did not react favourably to the suggestion of blanket foreign exchange allotment which could be interchanged for equipments and machineries as the Government of India will never agree to it.

A list of some of the imported plants and equipment needed, with notes on performance submitted by Shri J. C. Dasgupta of Calcutta Chemicals is given in the appendix II*.

130. In India, recently there has been considerable progress in the manufacture of pharmaceutical machinery and laboratory equipments. Import of equipments for Chemical Plants from outside has somewhat diminished. Some of the manufacturers were quite satisfied with the

* Appendix II has not been printed.

quality of the equipments available in India, others were not entirely happy with indigenous products. Articles made of stainless steel may be manufactured in some of the existing concerns in India, provided the necessary licence for the steel is made available to them. The Commission feels encouragement should be given to such manufacturers—which will not only help the drug industry but also give an impetus to the manufacture of such equipment.

131. Equipments for distillaries of complicated nature have also been manufactured in India. Tanks, Heat-Exchangers, Filters, Evaporators, Condensers, Air-Blowers, Air-Compressors, Air-Conditioning Plants and equipments, Air-Driers, Air-Filters, Autoclaves, Agitators, Centrifugal Machines, Dehydrators, Dissolving Plants, Driers, Emulsifiers, Mixing Plants, Edible Oil Filter Mixers, Oil Separators are being manufactured by a number of concerns in Bombay and Calcutta.

132. Optical instruments and potentiometers, precision colorimeters are generally not available in India. A Calcutta concern however is making microscopes with oil immersion magnification upto 1,500 magnification. The National Instruments Factory in Calcutta, a Government of India undertaking, is capable of making such microscopes with imported blanks.

133. Specialised electrical equipments like photo-electric colorimeter and spectrophotometers are imported; but pyrometers, dial thermometers and pH metres are now being manufactured in India. Japanese microscope of 2,000X with 4 objectives with microphotographic camera is valued at Rs. 1,200 plus import duty, against similar equipment from European countries at Rs. 3,000. The Commission would recommend to West Bengal Government that manufacture of specialised microscope should be stepped up. So long this is not done, they should allow import of microscopes for drugs laboratory.

134. Pharmaceutical processing may be considered under the following headings:

Sterile Products,

Tablets, Capsules, Granules & Pills.

Grinding and extraction of drugs.

Liquids.

Ointments,

Suppositories.

135. For sterile products aseptic precautions are necessary, which consist of filtration and conditioning of the air. Electromatic filters, Precipitron type is, according to the report of the Anglo-American Productivity Council Report on Pharmaceuticals (1951), 91.5 per cent. efficient compared to 53.5 for fabric filter. However, in view of the cost and specialised care needed for maintenance of the former large-scale adoption is not possible. However, should any firm need this type of installation, it should be possible to have this installed through some of the Air-conditioning Companies of the city importing essential components. For cabinets and screens stainless steel and glass are the principal materials. Fabrication according to specifications should be fairly easy. Requirements for preparation of containers and rubber closures for injections are specified at page 274 of the Indian Pharmacopoeia (1st Edition: 1955), and are similar to those at page 327 of the British Pharmacopoeia (1958). Autoclaves and sterilising ovens of conventional design are available in India. Filter Press, Sparkler type, is said to be not available. This can be imported, as also Filter Gandles, specially as candles are inert and therefore do not affect the pH of the filtrate.

136. In the manufacture of Tablets, Granules and Pills, machines are required for granulating, wet shifting, wet mixing, dry shifting, sieving, compressing and coating.

137. Of the machines that are required, the following are not made locally and have to be imported:—

(a) Granulating machine,

(b) Shifting machines,

(c) Coating and Polishing Pans.

(d) Integrators.

138. Single Punch Tablet Making machines are being indigenously made and are quite good and serve the purpose, but Rotary type machines indigenously manufactured have not proved to be satisfactory.

139. Tablet Counting and Strip Packing machines are available locally and give fairly good performance.

140. Use of Suppositories has increased of late, but machineries for their manufacture or packing are not available here.

141. Pill making machines are not available indigenously; their demand is also negligible in view of gradually diminishing use of pills.

142. Empty Capsules are not yet manufactured in India and have to be imported. Nor the machineries for their manufacture are available indigenously. The same supplies to machineries for filling and sealing capsules.

143. Manufacture of Tablets, Capsules, etc., requires air-conditioning units and utilisation of vacuum pumps—both of which are available in India at present.

2.4. ADEQUACY OF FINANCIAL RESOURCES

144. Even a cursory examination of the financial position of the drugs industry at various levels disclose certain interesting trends. It has, of course, not been possible for the Commission to examine critically the assets and liabilities position of the various units of producers which may be divided into Public Limited Companies, Private Limited Companies, Proprietory, Partnership, State Control and Local Bodies. It has also not been possible to make a complete capital analysis of all these various organisations engaged in producing drugs, nor all the relevant information has been submitted to the Commission by all of them. There is another difficulty. A drug industry is not always confined to manufacture of drugs only, but is also interested in the manufacture of cosmetics, food, etc.

145. A detailed examination of replies received discloses the following facts in respect of each group, taking the average of three years preceding that for which data are available;

Various groups of Cos.	Total number of Cos. under each group.
Public	38
Private	76
Proprietory	77
Partnership	31
Local Body	1
State Control	2
Total ..	225

146. The categorised division of the capital structure of the firms received in the Commission's office is somewhat like the following:—

Total Firms—225.

Category.	Less than 5,000.	5,000 to 50,000.	50,000 to 5,000,000.	Over 5,000,000.	Particulars not available.
Group	A	B	C	D	E
Public	..	3	27	7	1
Private	1	33	40	2	..
Proprietory	11	53	13	..	..
Partnership	1	15	15	..	..
State Control and Local Body.	..	..	..	..	3
Total ..	13	104	95		

147. In the Public group of companies, the total amount of capital invested appears to be about 15 crores of rupees. Private Limited companies have invested about 4 crores of rupees. In comparison with these, Proprietory and Partnership business concerns did not account for more than rupees 40 to 50 lakhs each. There have been profits and losses correspondingly and the method of financing is not only by the issue of authorised and subscribed capital but also by debentures and other loans. So far as big companies are concerned, they are sound and are apparently not in financial difficulties.

148. Take the case of a particular company. The paid up capital of the company, which belongs to Group D, is about 78 lakhs of rupees. They have been able to create, over a period, a reserve of more than rupees 67 lakhs. Such concerns may be left to find their own resource.

149. The second category of concerns require more attention. Some of these fall in category 'C' i.e., with a capital of 5 to 50 lakhs. They are apparently doing good business.

150. A few concerns keep a large portion of their assets in liquid form or in gilt edged securities. Credit accommodation from Bank or credit institutions do not present any difficulty to them.

151. Another company of established repute and of the same type as above with a capital outlay of rupees 5 lakhs, possessing licences for Biological and Non-Biological production with raw materials both indigenous and imported, claimed:

Cost of distribution—3.7 per cent. of the total turnover;

Cost of transport—8.3 per cent. of the total turnover;

Technical services—8.1 per cent. of the total turnover.

Their Sale with profit or loss:—

Years	Sale	Profit	Per cent.
1959	.. Rs. 20,10,642·03	Rs. 9,831·51	0·48
1960	.. Rs. 20,75,696·28	Rs. 17,613·83	0·87
1961	.. Rs. 22,47,903·23	Rs. 23,502·36	1·4

152. The concerns with a capital 5 to 50 lakhs also do not require much financial support as the analysis of the above cases show, but for some of them, and particularly for those in the next category (below 50,000 to 5 lakhs) financial accommodation would be necessary.

153. This group is mostly owned by the middle class Bengalees and the boards of directors consist of a number of medical men and scientists, and as such appear to be keen on maintaining a high quality of manufacture and they try to observe those ethical values which, the Commission considers, are conducive to the welfare of the industry. Their financial arrangements are not always satisfactory. They sometimes have difficultly in getting easy accommodation from banks.

154. We now come to the last group, which are numerically large and are difficult to deal with namely, the small Units. A capital analysis of the Proprietory and Partnership firms is of interest:—

Proprietory Firms

Capital	Loan Capital.	Reserve	Profit	Loss	Remarks
Rs.	Rs.	Rs.	Rs.	Rs.	
..	10,000	35,012	9,610	..	
10,278	3,000	..	2,775	..	
5,001	..	..	..	3,548	
4,529	16,950	..	3,030	..	
3,52,689	3,48,904	9,321	60,959	..	
15,241	1,100	..	3,284	..	
10,863	12,000	..	9,090	..	
15,446	..	..	..	..	
79,593	..	..	19,701	..	
20,025	..	..	2,341	..	
8,395	3,000	..	1,765	..	
11,613	29,147	873	4,085	..	
2,797	..	..	3,842	..	
3,545	88,052	..	8,960	..	
23,359	..	..	6,498	..	

Partnership Firms

17,745	12,877	..	7,368	..	
22,002	3,28,000	..	..	44,971	
..	12,758	..	..	1,275	
4,063	..	..	6,451	..	
23,065	13,400	7,236	726	..	
53,389	9,985	..	36,528	..	
2,824	..	..	828	..	
27,301	..	..	2,800	..	
19,89,96	..	8,590	72,462	..	
15,052	..	..	5,194	..	

155. These firms sprang up after the Second World War, which synchronised with the influx of refugees from East Bengal. Hard pressed in the struggle for existence, many with a feeble background of Chemical manufacture or a degree in science, took to manufacture of drugs. When they went into business in 1946-47, the Drug Rules had yet to be enforced. These formulations were sealed in bottles, labelled and sold to another group of refugees. It is still a common sight to see one of these men trudging along the footpaths of Calcutta from drug shop to drug shop vending these formulations and eking out a submarginal existence from low Commission sales. These firms did not have the wherewithal for manufacturing intermediates for production of synthetics and other highly specialised products like Antibiotics. Therefore, they took to what they thought was the easiest to prepare, viz. Water for Injection. To a number of medical practitioners Water for Injection merely meant double distilled water. Further, a number of witnesses in their evidence disclosed this. Possibly some small manufacturers took advantage of this ignorance and started ampoulising double distilled water and distributing them throughout the country. When a hue and cry went up, the administration came down heavily on them and some of the firms had to be closed down. The Commission felt unhappy over the closing down of these small manufacturers, but at the same time it cannot be denied that some of the mushroom firms should not, in the first instance, have been licensed and the system of licensing by the State authority was, to say the least, casual. The Commission would, therefore, suggest the following remedies:

(1) A fully developed Industrial Estate should be provided where land and other facilities would be available for pharmaceutical industries.

(2) A Drug Testing Laboratory should be set up on a co-operative basis. If necessary, Government may be asked to participate.

(3) These middle and lower class producers, who often fall a prey to the distributors acting as middlemen and become 'benumdar' entrepreneur for themselves, should be protected.

(4) It will be desirable for the small manufacturers to concentrate in the beginning on the production of a selected number of items.

(5) Government should render help to such concerns until they are able to stand on their feet.

2.5. QUALITY CONTROL

156. An integrated industry like Drug Industry must have an error-proof system of assay and assessment of raw materials, intermediaries and end products. The evaluation at every stage involves complicated qualitative and quantitative assessment and analysis. Modern statistical method of sampling and compilation and analysis of the results of observation call for higher specialised skill in Statistical Quality Control Methodology.

157. Quality Control of drugs and the products from them, whether ethical or magisterial, should ensure adequate degree of purity of the ingredients. Pharmaceutical quality control is unique in its elaborate scientific discipline, as besides chemical analysis, microbiological methods, biological assay and hygienic conditions have to be maintained.

158. Identification of raw materials require thorough knowledge of pharmacology and chemical analysis. Quality Control Chemist assays a product and then specialists give it a pharmaceutical form. The question

of compatibility and stability come in, and delicate pH balance of some of the products are to be ensured. As an example, a summary of stages of production of an antibiotic is given below:

(a) Selection of a suitable strain of micro organism followed by culture and storage at between -10°C and -30°C.

(b) Choice of medium for growth of the micro-organism and synthesis of the antibiotic by the enzyme system of the micro-organism.

(c) Maintenance of aseptic condition in the air-conditioned transfer rooms for transfer of micro-organism to fresh medium.

(d) Control of fermentation of the charged medium by control of temperature between +0.05°C, with cooling arrangements as during fermentation heat produced may kill the organisms. Foaming has to be controlled by Silicone or vegetable oil in proper dosage.

(e) Separation of the metabolite from the micro-organism in a rotary filter with a knife discharge.

(f) Extraction of the antibiotic by precipitation as in the case of tetracyclines or by solvent as in the case of penicillin.

159. At every stage the Quality Control Chemist should be able to detect changes brought about by faulty processing and errors in observation. A check list for each batch should be maintained. The in-plant control:

(a) Ascertains identity of raw materials used;

(b) Checks temperature, pressure and humidity;

(c) Ensures hygienic conditions, correctness of blending.

This should be followed by check on—

(a) Packaging so that drugs which prima facie appear not to conform to standard are rejected.

(b) Correct labelling.

160. It is not possible for small manufacturers to afford such elaborate control organisation. Therefore, they should not be permitted to manufacture such drugs.

Every group of such modern drugs requires separate control measures.

161. It is true that quality control aims at ensuring supply of safe and effective drugs to the consumers. So, it is argued, this should be the responsibility of the State. In view of the delicate quality control involved in production of modern synthetic drugs as well as drugs from animal source, the Commission is strongly of the opinion that State Government should have adequate scientific personnel and testing facilities which will enable the State Drug Control Laboratories to draw samples from intermediate stages of manufacture of such synthetics etc., for being tested. This would essentially be for the purpose of exercising control over the final production, but would also afford the opportunity for studying improvement in manufacture and giving guidance to the manufacturers. Even then, control by and large must be exercised by the manufacturers. The State should advise, assist and ensure that such control is being exercised. Such control should not interfere with the industry. Inspection by State should be positive, that is, after a fault is detected the firm should

be advised how to correct it and there should be a follow-up to ensure that it has been corrected. The manufacturer, in his turn, should furnish the State with all available information and the following in particular:

(1) Active ingredients and quantities;

(2) Stages of manufacture;

(3) Indication;

(4) Shelf-life.

The clearance by the State should not be construed to signify guarantee of cure, nor a substitute for periodic monitoring by Drug Inspectors.

Quality Control in Some Other Countries

Argentina

162. Control is through the Pharmacological and Therapeutic Society of the Argentine Medical Society. On the basis of suggestions of Prof. A. J. Bendonis of Buenos Aires, a permanent Pharmacopoeia Commission has been constituted by the Ministry of Social Welfare and Public Health as the earlier Commission constituted in 1931 could not function effectively. Without a live and complete pharmacopoeia, quality control is not possible. (Vide WHO Monograph WHO/PHARM/EXX/17.)

Present control regulations cover qualitative and quantitative analysis prior to marketing of a product. Detailed information is to be given to a Medico-Pharmaceutical Advisory Committee. After acceptance by the Committee, Government subject samples to further analysis and finally permit its sale.

Austria

Pharmaceutical Speciality Regulation of 1947 controls examination of drugs prior to sale. New drugs are put in the market quickly for commercial reasons. Inplant control is on scientific basis. But it is recognised that small and medium concerns cannot afford such costly investigation. The State, therefore, analyses the products prior to sale. The producer furnishes all available and required data, chemical as well as physical, in scientific terminology.

The State examines the claim of therapeutic value and if found deficient, the drug is rejected. There is a right of appeal to an Appellate Tribunal convened by the Federal Ministry for Social Administration, composed of representatives from:

(1) Federal Ministry for Trade and Reconstruction;

(2) Medical Corporation;

(3) Pharmacist Corporation;

(4) Wholesale Drug Trade Organisation;

(5) Social Insurance Funds;

(6) Pharmaceutical Manufacturers Association.

Competent University Professors are co-opted.

Switzerland

The large concerns exercise analytical control during manufacture in their own Control Laboratory on the following lines:

(1) Physical test, that is examination of taste, odour, specific gravity.

(2) Molecular Structure analysis.

United Kingdom

In-plant control is the basis of quality control in addition, competition compells the firms of standing to exercise strict quality control at every stage. Of course, the British Pharmacopoeia is of great assistance to the manufacturers. This is kept up to date.

The first London Pharmacopoeia was dedicated to James I published by the College of Physicians in 1616. The professional bodies of Scotland and Ireland produced their Pharmacopoeiae in 1699 and 1807 respectively. Soon, the inconvenience of having 3 texts was recognised and a Committee was set up by the General Medical Council, who brought out the first edition of the present British Pharmacopoeia in 1864. This was followed by the appointment of British Pharmacopoeia Commission consisting of medical and non-medical experts, with a permanent Secretary New editions were published in 1932 and 1948. An Act of Parliament of 1950 described the Pharmacopoeia as "to contain such description of the standards for and such notes and other matters related to medicine, preparations, materials and article used in the products of medicine, surgery and midwifery, as the Council may direct. "The present British Pharmacopoeia (1963) contains mearly 1000 monographs on preparations and antibiotics, glandular products, vaccines, sera, sulfa drugs, synthetic drugs as well as surgical materials and radio-active preparations. The old phyto-chemicals, like Atropine, Digitalis, Morphine and Chinapod continue to figure in the pharmacopoeia. The new edition of the pharmacopoeia is due in 1968. In England, law plays a secondary role in enforcing the standard of drug manufacture.

United States Of America

In-plant control is highly developed and check is adequate as the Thalidomide case has revealed.

As Quality Control of modern therapeutic products need staff of very high calibre, and quality control is a necessity, there is concentration of production of specialised drugs in the hand of a few. They control the market and the high level of concentration compelled the American Government to constitute a Committee of the Judiciary to study the administered prices of drugs. They realised that the nature of demand for ethical drugs with respect to price is inelastic and any lowering of price would divert the saving to other commodities. The question before them was one of public health and welfare. The Committee did not address itself to the question of standards as primarily concerned with price; but, nevertheless, there are interesting statements by various witnesses which show that the system of inplant control is highly developed in this group of specialised drug manufacturers. The reputation of supplier and the professional integrity of the manufacturer are the two outstanding factors which operate in the American drug industry to give it a unique position in the world. Therefore, as in some other countries, Hippocratic oath is taken seriously.

American Pharmaceutical Industry periodically take back from the druggists medicines whose shelf life is over. Although labelling is adequate, yet for maintaining their good name the manufacturers themselves sent down representatives to check stocks and remove from the shelf drugs which may be presumed to have lost their potency through passage of time. Dr. Eugene N. Beesley, President of Eli Lilly & Co., said in a testimony before the Kefauver Committee of the United States Congress:

> "* * * * ethical pharmaceutical manufacturers accept a greater burden of responsibility than most other manufacturers. At this moment, for example, Lilly is maintaining huge stocks of polio vaccine which represent potential protection against this dread disease for millions of children and adults. Inspite of the fact that little vaccine is being used at present, we feel a continuing obligation to be prepared for sudden increases in demand resulting from threats of epidemic.
>
> * * * * Vaccine not used within a 6-month period must be destroyed, and Lilly replaces out-dated vaccine with fresh stocks at our own expense. During the past 5 years we have had to destroy the incredible total of more than 14,500,000 shots of out-dated polio vaccine, vaccine which was produced with costly and painstaking care. This may or may not be 'good business', as that term is normally used, but it is the kind of obligation which, as a pharmaceutical company, we accept."

Mr. Connor, President of Merck & Co., explaining the refined quality control processes, stated:

> "Indicative of this great effort to insure quality and uniformity are the standards set for each batch of every product we make. The list of different specifications to which our steroid products must conform in order to bear our trade-mark is a lengthy one. Every imaginable aspect is controlled by inspection and testing. Thus standards are set and tests are required to prove the quality and amount of each substance going into the manufacture of the product. Often the range of the amount of active drug allowed is rather narrow and where an assay procedure itself is known to have an error, say 1 per cent. to 2 per cent. an extra amount of drug is used to balance such a possibility. Not only is the amount of each substance controlled but the form of it may be subject to passing the most rigid requirements. Thus in our opthalmic suspensions which come into contact with the eye, the size of the steroid crystals must fall within narrow limits. A representative specification reads:
>
> 'Particle size:'
>
> A. Microscopic: No particles greater than 200 microns. (Occasional fibres should be ignored). No more than five particles per drop of suspension in the 50—to 200—micron range. Minimum 99 per cent. (by number) less than 30 microns or minimum 65 per cent. (by number) less than 10 microns (tentative).
>
> This process of testing is pursued endlessly through the manufacturing process. Thus in making one of our ophthalmic solutions no less than 121 separate tests are made before Merck Sharp & Dohme is ready to assign its trade name. Subsequent to manufacture, 750 more separate tests are made to check stability.

On this single product 871 separate tests are required to produce the product Merck Sharp & Dohme calls Neo-Hydeltrasol. Incidentally, these tests require at least several hundred man-hours of skilled, conscientious labor, not to mention the most advanced equipment.

The 'company conscience' is another name for quality control. The conscience of Merck Sharp & Dohme and Merck operates to give the doctor and the patient exactly what is expected".

The Americans take a legitimate pride in the advance of ethical drug industry, and this pride in their products and the prestige are the surest guarantee for ensuring that drugs conform to the prescribed standards during the process of manufacture. The evidence of Mr. Connor is revealing. He states that 871 separate tests are required to produce one of their products—Neo-Hydeltrasol.

2.6. EMPLOYMENT OF DULY QUALIFIED TECHNICAL EXPERTS

163. The need for qualified technical staff to exercise quality control during manufacture is very great in West Bengal. Even if the universities turn out qualified men in adequate numbers, the condition of the Testing Laboratories, with only a few exceptions, is such that these men would be of no use. In the case of a number of small units the Commission noted with concern that part-time science graduates, with no knowledge of pharmacology and far less of the manufacture of chemicals are in over-all charge of production. It is true that most of these concerns are like dispensing chemists' shops. Even then, as they have been licensed to manufacture formulations they must have suitably trained personnel.

164. For candidates for this branch of technical education, a sound knowledge of general science is indispensable. The crucial question is the need of qualified teachers. The controversy in England over Robin's Report and flight of scientists from the United Kingdom to the United States are problems in India also. The "brain drain" referred to by Mr. Grimond of the Liberal Party in an address to the London Rotary Club is partly due to better remuneration but it is equally true that lack of research facilities stand in the way of qualified scientists. This is so in West Bengal also. Very few first class men are attracted to the teaching profession because of inadequate research facilities. Small drug industries are unable to sponsor training of technicians. Technical institutions located in and around Calcutta will go a long way to help the situation.

165. For pharmaceutical quality control the organisation should be divided into:

(1) Administrative branch,

(2) Inspection branch,

(3) Laboratory.

The administrative and the executive branch should be manned by Science Graduates with adequate experience of administration.

The Inspection service should be manned by Quality Control Experts who have detailed knowledge of process of manufacture and are conversant with the principles of statistical quality control, so that they can draw samples and send them over to the laboratory wing for testing and maintaining accurate record of results and also ensure identification of the various stages.

The laboratory service would include analysis or examination of samples and therefore three types of laboratories would be needed, one for chemical and pharmaceutical analysis, the other for physiological and pharmacological tests and the third for bacteriological and immunological examinations.

166. Unfortunately very few concerns employ or can afford to employ such specialised staff. Even though some of the manufacturers are willing to spend money they find difficulty in getting qualified personnel as well as the right type of equipment for testing for want of foreign exchange. It has been suggested that quality control for testing of manufacture can be done at a centralised Government laboratory. This is a good suggestion but the Commission feels that the manufacturers should have testing laboratories attached to their organisation and feel proud of their own manufactured products. The Commission also feels that it may be desirable to establish Government Laboratories for production control as a cross check in the matter of production, now and then. Some of the concerns could pool their resources and have a laboratory of their own or send their samples to the laboratory of other concerns by arrangement. As the map of the location of industries given at the end of this Report will show it will not be difficult for small concerns to come together and contribute and maintain the laboratories suitable for testing their products.

167. The Commission would also recommend that in view of acute shortage of technical personnel to man bacteriological and immunological laboratories and specialised assay of glandular products, the manufacture of these items by concerns who have not the adequate laboratory facilities and/or suitable technical personnel to man these laboratories should be prohibited.

168. Excepting for some large units, none of the laboratories employ experts as such, and tests are carried out by ordinary medical men or Science Graduates as the following figures will show:

Staff	Number employed
(a) Chemical Engineer	45
(b) Pharmacist	77
(c) Biochemist (M. Sc., in Biochemistry, or M.Sc. with Biochemistry as special paper)	29
(d) Micro-Biologist	34
(e) Persons with registrable Medical qualification e.g. L.M.F., M.B. B.S., M.D., etc).	115
(f) B.Sc., or M.Sc. [with Chemistry as a subject. Those mentioned in (3) not included.]	590
(g) Laboratory Assistant (qualified)	446
(h) Other workers	6,413

169. According to the returns from drug manufacturers, the industry in West Bengal needs the following immediately:

Chemical Engineers	27
Pharmacists	40
Biochemists	23
Micro-biologist	37
Chemists	313
Laboratory Assistants	239
Other semi-technical hands	2,809

170. No. of seats available for degrees in Pharmacy Chemical Engineers in India are:

Birla Institute, Sindri, Bihar (B.Sc.)..	30
College of Engineering Technology Hauzkhas, (Delhi University)	No. not knwon
Delhi Polytechnic (B. Che.)	30
Madras University (B. Pharm)	25
Madras Institute of Technology	—
Bombay University (B. Chem. Eng.)	60
(B. Pharm)	15
Gujrat University (B. Pharm)	75
Nagpur Institute of Technology, Chemical Engineering ..	36
Punjab University (B.Sc). Chemical Engineering ..	32
National Sugar Institute, Kanpur, short courses in manufacturing.	12
I.I.T. Rampur, Chemical Engineering	25
Beneras Hindu University (B. Sc.) (Chem. Eng) ..	30
Beneras Hindu University (B. Pharm)	22
Jadavpur Univesity (B. Pharm)	25
Jadavpur University Calcutta (B. Ch. Eng)	60
Calcutta University, M. Tech. in Chemical Eng. (Chemical Tech).	36
I.I.T. Kharagpur, Chemical Eng.	35
Saugar University, (B. Pharm)	Not known.

171. Therefore, there is no difficulty regarding Chemical Engineers. Regarding pharmacists the Commission understands that the Jadavpur University have made a start. Biochemical and Microbiological work can be done by medical men. Regarding Chemists, an ordinary chemistry student will not be able to do the work. Therefore, there should be arrangement for in-service training of the existing chemists and specialised training for B.Sc., students who signify their intention of joining the drug industries as chemists. Similarly students who have passed the Higher Secondary Examination of the Board of Secondary Education West Bengal, in the Science stream should be trained as Laboratory Assistants. Study of quality control and stability of drugs requires intimate understanding of the properties of continuously developing range of therapeutic agents. In England there are provision for Pharmacy degree in the University of Glasgow, Leeds, London, Liverpool, Manchester, Nottingham and Wales. In India the subject has so far not attracted adequate attention of the University Authorities excepting in the Universities of Madras, Bombay, Gujrat, Punjab, Varanasi and Saugar, which accounts for a total number of 127 seats. The facilities for graduation in pharmacy are inadequate in West Bengal.

172. The Commission recommends that all the Universities should have Four Years degree in Pharmacy where the students can have facilities for practical work in manufacturing establishments for learning the process of manufacture and quality control. The curriculum should include Pharmaceutical Engineering, Pharmaceutical Chemistry, Pharmaceutics, Pharamacognosy and Pharmacology. Pharmaceutical Chemistry will give the basis for understanding the structure and properties of drugs and analysis of raw materials used in manufacture. Pharmaceutics will give the students a training in presentation of material for administration, i.e., whether it should be given as pills or as mixture or as injections. It would also inculcate in them a basic knowledge of Microbiology and of unit process. Pharmacognosy will provide the necessary training for identification of medicinal plants and their constitutents. For this the Forest Department of the Government which is manned by some of the best available men on the subject should be asked to assist both with lectures as well as with demonstration and field study. Pharmacology is of course a more difficult subject and it should be taught by experts. Therefore the teacher should be recruited from medical men with adequate clinical background and with knowledge in applied physiology, pharmacology and therapeutics. Demonstrators should be able to teach quantitive measurements of biological effects by statistical analysis. Some of selected Universities should have curriculum for postgraduate training. In the United Kingdom they have such facilities at Brighton for Therapeutics, at Cardiff for Radio-activity, Colchester for Chemical therapeutics, Glassgow for Pharmacology, Cheshire for Medicinal Chemistry, Manchester for Pharmacological testing of drugs.

173. In addition to the in-service training and experience the Commission would recommend Refresher Course for all categories of technical staff engaged in routine tests. The Refresher Course would also be at the Universities.

174. Intensity of training and effectiveness will depend largely on those who undertake the profession. The development of sound ethical codes among Pharmacists will depend on themselves, as voluntary control through corporation is the pattern in democratic countries.

2.7. MEASURES ADOPTED BY MANUFACTURERS FOR TESTING DRUGS BEFORE PLACING IN MARKET

175. The examination of pharmaceutical preparations prior to release for sale has assumed importance. It is most essential, therefore, that the State Drug Control Organisation should have adequate facilities and staff competent to carry out complicated examinations of a large number of drugs.

176. In Russia, the State is the sole manufacturer. Pharmaceutical preparations are subjected to check analysis at laboratories supervised by the Pharmaceutical Board. Thereafter, these are issued to the various drug stores. The second check, only by organo-chemical analysis, that is check by colour, odour and homogeneity, is done at the drug stores where the State maintains an organo-chemical testing laboratory manned by good pharmacists. They check 10 per cent. of the products that go out for sale.

177. In Canada, it is recognised that detailed regulations in this connection would become embarrassing. Although the Canadian administration recognises the necessity for control of potency of drugs and purity of food products, they appear to be satisfied with random sampling, as competent analysis of every lot of products in any event is an impossibility. Law can only be effective if there is an organisation to enforce the provisions of law. Canadian Government recognises, and the Commission agrees,

that mere punishment will not improve the standard of ethics among the drug manufacturers or those who vend adulterated or substandard drugs. The effect of incompetent control is disastrous, as it not only does nothing to the dishonest manufacturers but also gives a false sense of security to the consumers.

178. In the United States, manufacturers generally do not disclose the formula of drugs which are under development. Introduction of new drugs is subject to compliance with the regulations of Federal Law and Drug Administration as to the relative safety for clinical use. Some, but not all, antibiotics are further subject to certification of each lot for potency by a federal agency.

179. In France, official approval is necessary for drugs which claim to be new and of therapeutic interest. However, if a drug used for a particular disease is claimed to be specific for another, it is categorised as a new one. As Prof. R. Hazard of Paris has pointed out in an article (vide—Organisation Mondiale De La Sante' of Oct. 27, 1959), Piperazine, first used as solvent for uric acid, is claimed to be a vermifuge, hence this is in the category of new drugs. New drugs are subject to preliminary approval by the Commission due Visa consisting of physicians and pharmacists.

180. Special categories of drugs which are released in the market are as follows:

A. substances which, in principle, can only be supplied against medical prescription: e.g., poisons—red label; addiction producing substances—red label; dangerous—green label;

B. substances regarded as not dangerous and supplied without prescription.

181. The system of control in the United Kingdom has developed over a number of years. The basic principles for this control are—(i) interest of public health, (ii) export trade, and (iii) encouragement of free trade and competition. According to British line of thinking, competition stimulates manufacture of quality products as the manufacturers take pride in their products. The Food & Drugs Act, 1875, administered by the local authorities which permits samples to be taken of proprietory medicines for analysis, has little practical application in testing a drug prior to its release to the market. The essential feature of control is the control exercised by the Proprietory Association of Great Britain, which is a trade association, and which, in addition to developing code of standards of advertising practice, also insists on analysis prior to release to the market.

182. The joint Sub-Committee of the Standing Medical Advisory Committee in U. K., reported on the safety of drugs. They emphasised the following:

(i) Testing toxic effects;

(ii) Clinical trials and assessment of therapeutic efficacy; and

(iii) Studying adverse reactions.

Sir Hughes Linstead, Secretary to the Pharmaceutical Society of England, is of the opinion that early legislation is needed as voluntary control may be subject to evasion.

183. The test for toxicity is carried out on animals and where possible, on human volunteers from the jails. Clinical trial is meant for establishing the correct formulation and dosage and for determining if the drug is habit forming. The other study about adverse reactions on the human system

is to be spread over a number of years. Therefore, there should be three technical sub-committees whose duties will be to study these and report back to the Government for legislation. Tests for toxicity and correct dosage would require detailed study, including study of variance.

184. The Commission made detailed enquiries among the leading manufacturers of West Bengal to ascertain if these control are exercised by them. Excepting for routine tests specified in the Pharmacopoeia, statistical control test for dosage, correctness of formulation and test for suitablility of drugs are not carried out by any of the concerns in West Bengal. However, the problem is not a serious one as yet, as the number of such drugs manufactured from basic materials administered in micro doses, specially synthetics, is very small. Most of these are imported and the monograph on them or other literature are adequate for the purpose.

185. The Commission would record a note of caution. Drugs which have not been fully proved, should not be permitted to be imported into this country, as apart from routine chemical, pharmacological and biological tests, no facility exists in India for studying other aspects of drugs.

186. The Commission would recommend:

(a) That Government set up Expert Committees to report back to Government for action after studying—

(i) Toxicity,

(ii) Results of clinical trial, and

(iii) Adverse effects of all synthetic and other drugs;

(b) That unproved and partly proved drugs should not be permitted to be imported into India;

(c) That those manufactured in India should first be cleared by a Technical Committee and distinctively marked, as is done in France;

(d) That vigilance should be exercised by manufacturers' organisations by voluntary control;

(e) That expeditious dissemination of information by the India Medical Association of adverse effects of drugs is desirable. As in the U.S.A., drug evaluation should be made by the Indian Medical Association, on the following lines:

(i) All pharmacological and clinical data should be referred to an Expert Body of consultants;

(ii) The experts should examine the monograph prepared by the Association;

(iii) The findings of the experts should be sent to a referee who is a member of the Association;

(iv) The monograph as amended by the referee should then be circulated to all the members of the Drugs Wing of the Association;

(v) The criticisms of the members should be finally considered and the final draft monograph published in the Journal;

(f) That drug analysis should be done by the Indian Medical Association, if necessary with financial assistance from Government and other sources.

2.8. DIFFICULTIES OF MANUFACTURERS IN PRODUCING DRUGS

187. Some of the difficulties faced by the manufacturers in producing drugs conforming to prescribed standards have been dealt with under sub-chapters (2), (3), (4), (5), (6), (7) and also in subsequent sub-chapter (9) of Chapter II.

188. Incidentally it may be stated that in the course of their investigations the Commission came to know of certain facts which, they feel, may cause some handicap to the indigenous manufacturers and may also adversely affect the ultimate consumers with regard to price. The Commission, therefore, suggest that Government should have the matter further examined. This is particularly with regard to the price of imported materials such as Vitamin B12, Sodium PAS, Aspirin, Ascorbic Acid, Sulphadiazine, etc. They are available direct from the foreign manufacturers in India or their accredited agents, as well as through the local manufacturers and dealers. Those who buy retail or wholesale direct from the agents of foreign companies get them at a cheaper price than those who obtain them from the local manufacurers. The latter have to sell the same components even without bottling or reprocessing at a much higher price. The results are interesting as may be seen from the following table:—

Name.	Landed Cost.	Price at which local manufacturers sell.
	Rs. nP.	Rs. nP.
Vitamin B-12	62·75 per Gram	221·45 per Gram.
I. N. H. ..	35·25 per Kg.	103·49 per Kg.
Chloramphenicol	157·00 per Kg.	524·24 per Kg.
Tetracycline	220·00 per Kg.	1,615·02 per Kg.
Ascorbic Acid	25·00 per Kg.	74·22 per Kg.
Vitamin B-6 ..	318·30 per Kg.	722·22 per Kg.
Sodium PAS ..	16·25 per Kg.	30·40 per Kg.
Aspirin ..	5·20 per Kg.	10·56 per Kg.
Sulphadiazine	38·50 per Kg.	60·26 per Kg.
Prednisolone ..	6·46 per Gram.	16·37 per Gram.
Penicillin ..	112·75 per B.U.	530·00 per B.U.
Malt Extract	1·11 per Kilo	3·72 per Kilo.
Niacinamide ..	26·82 per Kilo	81·54 per Kilo.

189. In the case of Tetracycline the price is Rs. 220 per Kg. for imported material, but the local price is Rs. 1,615 per Kg. that is almost eight times. The price of intermediary and basic chemicals, from which almost all these items are manufactured in India, is almost the same as the price quoted by them for import of finished products. For instance, for Sulphadiazine the c.i.f. price is sh. 45 per Kg. whereas the intermediate from which indigenous manufacturers are producing Sulphadiazine is also sh. 45 per Kg.

190. The Commission is definitely of the opinion that procurement of specialised intermediates and such raw materials which cannot be had in India, should remain in the hands of the normal trade channel. Should,

however, the industry face any difficulty in this respect due to foreign exchange problems, the matter should be represented to the Government for redress. In some cases, the increase in recent years has gone up by 100 to 300 per cent. Ephedrine Hydrochloride has shot up from Rs. 22 to Rs. 82. Price of Folic Acid has gone up to Rs. 57 from Rs. 39.50 per Kg. Caffeine from Rs. 25 to Rs. 35 per lb..

191. It is, therefore, desirable that Government should start indigenous manufacture of intermediates and penultimates and direct sale to the licensed drug manufacturers.

192. It has been brought to the notice of the Commission that during its sitting the State Drug Control authority have all of a sudden become over-active and are insisting on:

(a) Air-conditioned production units:

(b) Installation of imported machinery:

(c) Change in the traditional filtration technique:

(d) Maintenance of sanitary condition in the neighbourhood.

Most of these may be beyond the competence of the smaller units.

In regard to (a), the Commission ascertained that adequate number of Air-conditioning Units at reasonable price are not available in India. Further, there is hardly any Freon or Arcton available, which are essential for running these units.

In regard to imported machinery the experience is that ampoule filling and sealing machineries, when operating at high speed, break down due to perhaps fluctuations in the pressure of gas and power supply. The ampoule sealing machinery can only operate successfully if a constant pressure is maintained. The pressure of the city's gas supply is subject to wide variation and sometimes stops completely. It is not possible for these units to have their own supply system.

The index *map at the end of this Report will show the location of the manufacturing units in Calcutta. Most of them are situated in insanitary surroundings of the city. The responsibility for cleaning of these areas lies with the Corporation of Calcutta. The Industry Department of the Government appear to have approved of the location and licensing of industry without the circumspection regarding sanitary conditions. As drug is a social commodity and its proper manufacture is of vital interest to the nation, the Commission would recommend to Government that full compliance with sanitary provisions under the Drug Rules must be a condition precedent for licensing new factory and approval of extension for existing ones.

193. The following other difficulties are faced by the industry:

(1) Inadequate supply of city's Gas at varying pressure. This has particular bearing on the sealing of ampoules.

(2) Inadequacy and break-down of the city's Electric supply system. For continuous processing, voltage variation and sudden stoppage, known as load-shedding cause disruption. Manufacturing schedule cannot be organised to take into consideration such break-downs.

(3) High cost of air-conditioning materials and non-availability of spare parts. It is reported that a particular concern is hoping

* Index map has not been printed.

to come into production of 'air-compressors' for air-conditioning units in Hyderabad by 1965. When this fructifies, the Commission hopes that this will afford some relief to the small manufacturers.

(4) Transport, as usual, continues to be a bottleneck for this industry as well as in others. Some of the industrial units could have been located in more congenial areas but for the city's transport system. The arterial roads leading into the city are so congested that there is considerable loss of time for workers to reach their factories.

The railway authorities also do not appear to have the requisite number of tank-wagons in proper condition.

Different types of tank-wagons are needed for transport of different types of liquid material. It is reported that there is acute shortage of these types of wagon.

The small manufacturers experience difficulty in the matter of loading as they do not have sidings, which they cannot afford as the quantities involved are not sufficiently large for the purpose. Even large manufacturers have difficulty in the matter as the cost is considerable and operation is entrusted to the normal operating section of the Railways.

(5) Suitable and necessary number of Weigh-Bridges are not situated at the manufacturers' sidings. This entails long distance movement in order to reach Weigh-Bridges, thereby causing avoidable expense and loss of time.

(6) There is no priority for movement of important bulk raw materials needed by the industry. Further, the railway authorities should give concessional rates for the transport of these light commodities.

(7) The purchasing authorities should restrict their purchases to bulk utility drugs and allow complete financial freedom to the heads of hospital organisations for purchasing specialised drugs of their own choice. The Commission understands that some latitude in this respect has recently been granted by the Health Department.

The Commission recommends that indigenous drugs manufactured from indigenous raw materials should be given priority wherever possible.

(8) The Central Government's import policy on Drugs should be further looked into. At present basic raw materials and intermediates are included in item 28 of the Tariff Schedule. According to the manufacturers this rate is very high and Central Government should lower the tariff in respect of certain basic intermediates and raw materials, manufacture of which is either not possible in India or not desirable from the economic point of view.

The State Assistant Director of Health Services issues essentiality certificates for import of plants, machinery and laboratory equipment which are not available from indigenous sources, but this requires the approval of the Jt. Chief Import Controller which is not always readily available nor is any adequate reason given for witholding the approval. On the other hand it has been

brought to the notice of the Commission that certain concerns which are manufacturing formulations from the pharmacopoeia of certain western countries and selling them under indigenous names in the local market. Obviously these concerns have received import licence for specialised equipments. The Commission considers this to be a serious matter and suggests that Government should enquire into it.

During the course of its sittings the Commission found, for example, an article which is known as Bamboo Camphor (Bansalochan) and is imported in large quantities from Indonesia, Sumatra and Singapore under the category of Drug. This is merely a calcarious substance formed inside a species of bamboo grown in these regions. It is supposed to be a panacea for a number of incurable diseases, like loss of eye sight and male sexual potency. While the Ministry of Commerce and Industry, Government of India, allows import of this type of crude drug, which is available from indigenous sources, to the extent of Rs. 20,000 every quarter, important equipment and machinery are denied import. Details of drugs imported during April 1961 to March 1963 are given in the appendix in Part III of the Report.*

(9) Shortage of raw materials of animal origin is another standing difficulty. It is reported that the amount of active drugs, which can be recovered from various organs of slaughtered animals in India, is low compared to other countries. The Commission is of the opinion, however, that this should not stand in the way of recovering whatever is recoverable. Government of Bombay appointed a Committee, known as Massani Committee, for studying the condition of slaughter houses in Bombay under their Public Health Department notification No. 6689/33, dated 10th January 1961. They recommended "proper collection and preservation of Glands and Organs in slaughter houses where at least 500 animals are slaughtered per day, by cold storage at below —150°C". They also recommended careful consideration of a note by Dr. B. K. Nandy. Details of this have been given in the chapter dealing with Raw Materials.

(10) Labour troubles and payment of bonus to workers continue to be the headache for this industry as well as for others.

(11) There is considerable over-lap in the matter of production of drugs in the industrial policies of the Central Government in the different plan periods. Those in the private sector feel that sudden encroachment on their field of operation in the manufacture of drugs will continue to cause uneasiness and, therefore, would likely to be a permanent deterrant against deployment of fresh capital or initiative for improvement of manufacture. With talks of Nationalisation in the air, the drug manufacturers' uneasiness has further increased. The Commission feels that the Government should categorically state what their policy is in respect of different category of drugs.

(12) The Commission has been informed that delay and harassment to which the drug manufacturers are subjected in the hands of subordinate officials, cause resentment and are, therefore, to the

*Part III of the Report has not been printed.

detriment to the interest of the industry. One way of lessening this evil would be to reduce the number of 'tiers' in the official machinery in so far as issue of licences is concerned. An advisory cell of the Drug Control Organisation, which we have recommended under appropriate head (see Drug Control Organisation at chapter 3(8), should deal with applications for import, licensing and other matters. This would greatly obviate some of the difficulties, including loss of time incurred by directors and senior technical executives of the drug industry.

2.9. EXISTING TAXES AND DUTIES

194. A multiplicity of Acts, Regulations and Rules which affect other industries as well, are also in force in respect of the Drug Industry, for example, Factories Act, for those who have boilers—Boiler Act, Employees' State Insurance Act, Employer's Provident Fund Act, Compulsory Deposit Scheme, etc. In addition to these are also the Drugs Act and the West Bengal Drugs (Control) Act, 1950, which are specific for the drug industries.

195. Under the new Finance Act, excise duty has been levied on patent and proprietory drugs. The manufacturers who display water for injection as Pyrogen-free are subject to Central Excise duty, and on the other hand medical practitioners will not accept these preparations unless they are labelled as Pyrogen-free. If indications of the nature of drugs are printed on the labels, they are classified as proprietory items and as such would be subject to additional duty. Drugs like Vitamin A and C are liable to deterioration under adverse storage conditions. Therefore, in the interest of the consumers, storage conditions have to be specified on the label by the drug manufacturers. But this would not be permitted by Central Excise authorities without payment of additional duties. Even slight variation in spelling of the drug attracts additional duty.

196. Patent and Proprietory medicines are differently defined by different authorities operating the relevant Acts.

197. Further, the Central Board of Revenue are taxing pharmacopoeial preparations as patent and proprietory medicines only because the labels are printed in slightly bolder type. The Finance Bill of 1963 provides for levy of ad valorem duty on medicines. This has made the issues even more complicated.

198. According to manufacturers, 7½ per cent. to 10 per cent. of this wholesale price of drugs is paid as duty prior to release from the factories. No refund is allowed for damaged, broken and time-expired drugs. Only 5 per cent. of the entire production is allowed to be distributed among physicians as duty-free samples.

Central and State Sales Taxes enhance the final price of drugs which have gone up from 1 per cent. to 2 per cent. and 3 per cent. to 10 per cent. respectively.

199. After the promulgation of the Medicinal and Toilet Preparations (Excise Duty) Act of 1956, some degree of confusion appears to have arisen in the minds of the drug manufacturers. The Commission during its sittings found that it had not been quite clear to the drug manufacturers whether the Central Act or the State Excise Acts govern the deposit and storage of duty-free alcohol prior to its being mixed with other ingredients for preparation of medicinal and toilet products. Prolonged controversies had taken place among drug manufacturers, State Government and Central Government even to the extent of litigation in a certain case.

200. To the Commission it appeared that medicinal preparations using alcohol during manufacture can be divided into two classes: (1) those preparations where the end product contains alcohol. Duty in these cases is apparently to be levied in accordance with the provisions of the M. & T.P. Act of 1955 which is a State Act; and (2) those preparations where alcohol is used in the process of manufacture, but the end product contains no alcohol. This does not attract duty either under the M. & T.P. Act of 1955 or the Bengal Excise Act of 1909, both of which are State Acts. Such cases apparently are governed by the Central Excise and Salt Act of 1944.

201. Apart from the fact that a clarification of the above mentioned points and a firm policy of the State and/or Central Government in its execution is essential for the guidance of the manufacturers. the Commission found no ground to recommend any relaxation or special concession for the Drug Industry in the matter of excise duty.

2.10. RECOMMENDATIONS FOR WEST BENGAL

202. Synthetic drugs are today in great demand and have to a large extent displaced other forms of therapy.

203. There is no dearth of talented chemists in West Bengal. The chief difficulties are non-availability of appliances and equipments and shortage of intermediates.

204. Acid-proof enamel vessels, alloy steel vessels, glass lined reactors, acid-proof valves, are some of the principal items which are in short supply.

205. Therefore, establishment of chemical engineering industry is the first requisite. It may be beyond the means of entrepreneurs of this industry to undertake the manufacture of such specialised equipments without financial aid from the State or other financial houses. The smaller concerns may get over the difficulty by forming a Syndicate or Corporation.

The manufacturers' represenatives who met the Commission on May 1, 1964, welcomed the idea.

206. The Commission would, therefore, recommend that possibilities be investigated by the State Government.

Scope:

(1) What are the items that should be manufactured wholly?

(2) What are the items that should be manufactured partly?

(3) What raw materials are available readily in the country?

(4) What are the items to be imported, from which countries, and their cost.

Capital:

Estimates of capital required should include—

(1) Cost of fixed assets,

(2) Working capital,

(3) Promotion expenses,

(4) Organisational expenses,

(5) Financing, and

(6) Expenses on foreign collaboration, if necessary.

Chapter III

3.1. DRUG CONTROL IN DIFFERENT COUNTRIES

Canada

214. Plant inspection is well-organised and has a legislative backing. Activities of the Inspectors are restricted within the provisions in the statute.

The essential features of drug control are:

(1) A standard pharmacopoeia;

(2) Law;

(3) An enforcement organisation.

Canada has a fairly satisfactory legislation on drug and food. There are some 25,000 pharmaceutical preparations. So spot checking cannot be depended upon for control of drug manufacture. Dr. G. L. Kalbfleisch of Ottawa states in a W.H.O. monograph that sanitary conditions are strictly enforced.

The manufacturing premises have to store raw materials and finished products properly, which includes proper identification of the items at all stages. The essential feature is control over the manufacturing procedure. Checking and identification of raw material is by the issue of Work Order or Production Sheet which indicate the particular lot of raw material to be used in each batch and the amount of such material to be used. It is extremely important that all materials used in the process of manufacture should be identifiable, as also the machines and the receptacles.

Control of the manufacturing procedures, however, cannot be enforced by legislative measures alone. Voluntary control by the manufacturers is essential.

This is followed by an analytical process for checking of mistakes. This control is not meant to slow down manufacturing procedure. The main function of the control laboratory is to check the quality of raw materials, which should afterwards be kept in quarantine until release for manufacture. It is recognised that the Inspectors have neither the time nor the competence to go over the entire process of manufacture of various complexes produced today. They only check whether the necessary equipments displayed in the laboratory are actually used.

Denmark

215. According to Professor S. A. Schou of Copenhagen, during the compilation of the Danish Pharmacopoeia in 1948 it became clear that specifications should be adjusted to the changing conditions. If the pharmacists were made to purchase raw materials from specially controlled and authorised dealers, it might be possible to maintain the specifications of identity and purity, placing only a part of the responsibility on the wholesale dealer. According to him, it must be clearly recognised that the final responsibility for identity of the substances must rest with the drug manufacturers themselves. Suitable, simple and quick methods of checking the identity of substances are necessary conditions in the country where a large number of specialised products are used in micro doses. The identity control system was developed by F. Reimers and his co-workers and has been published in the form of a file containing 650 cards and brief instructions. Copies of these files have been distributed throughout the country. This has proved to be of great value in practice.

The system is based on:

(1) Sense Test;

(2) Micro solubility Test;

(3) Selected Chemical Test;

(4) Melting Point Determination, including mixed melting points.

The apparatus required cost less than £25. The control is exercised only by the manufacturers themselves on a voluntary basis.

Switzerland

216. All the cantons, including the principality of Lichstenstein jointly drew up an Intercantonal Convention for unification and regulation of the marketing of drugs. The Intercantonal Office is in Berne. The cantons do not license sale of any medical speciality unless cleared by the Intercantonal Office. They set up their first laboratory as late as 1953. The control, thus, is voluntary and is reported to be effective, one reason of course being that the Swiss manufacturers have to compete with U.S.A. and Germany in the world market and with Italy nearer home.

United States of America

217. Control is exercised principally through the Federal, Food and Cosmetic Act. The Law deals with purity, potency, safety and labelling, and also controls distribution of drugs.

The certification procedure applies to Insuline, and five types of antibiotics, which involve testing each batch in the control laboratory. "New Drugs", that is drugs which have not yet generally been recognised by medical experts as clinically safe, are subjected to vigorous control. The manufacturer has to satisfy the Federal Authority that the manufacturing process and quality control in the factory are sound. Other drugs are not subjected to pre-marketing control, but they must conform to the specifications in the U.S. Pharmacopoeia.

The Food and Drug Administration has laboratories at Washington and 18 other principal cities in the States. Chemists, Pharmacologists, Bacteriologists and Antibiotic Specialists test drugs there. Inspectors visit the plants and their comments are sent to the manufacturers for action. The inspectors also collect information for amendment of regulations.

There is an awareness that the control over 'other drugs' should be more vigorous, as well as over illegal distribution of drugs because of abuse of barbiturates and amphetamines by juveniles.

Control over Vaccine and similar drugs is vested in the Public Health Authorities and those for veterinary use in the Agriculture Department.

U.S.S.R.

218. The manufacture of all the drugs is by the State. The testing is done in the Control Laboratories of the Pharmacological Administration. The testing is rigorous as will appear from the following quotation from the 14th July, 1961, issue of the 'Medical Worker', a soviet journal:

> "In the last year, for example, 112 various drugs were sent to us—ampoules, tablets and others. And it is deplorable that 75 per cent. of them did not meet the requirements of the official governmental pharmacopoeia and the technical standards."

United Kingdom

219. The control system in Britain has public interest and safety as its principal objects. Legislative interference with production is minimum. The system in effect encourages healthy competition among manufacturers themselves.

Government control is substantial and through a number of statutes, the first of them being the Food and Drugs Act of 1955—successor to the series commencing from the Sale of Food and Drugs Act of 1875. In the U.K., Food and Drugs Act are classed together. This has certain advantage and also disadvantage. The advantage is this that the same rigorous control is exercised over the sale of foods as over the drugs. The disadvantage is that Inspectors cannot have adequate expert knowledge to test both of the items.

The Act seeks to prevent the preparation and sale of injurious and adulterated food and drugs, and their false labelling. Sub-section I of section 2 makes the sale of food and drug which are "not of the nature or not of the substance or not of the quality of food or drug demanded by the purchaser" as an offence. Sub-section 1 of Section 6 makes it an offence to sell any food or drug, or display any such material for sale with label which falsely describes the food or the drug or "is calculated to mislead as to its nature, substance or quality". It also prohibits the publication of advertisement which falsely describes any food or drug, or is "calculated to mislead as to the nature, substance or quality of any food or drug". This Act is administered by officials appointed by local authorities. They make test purchases and get them analysed.

Prior to 1941, proprietory medicines were sold without declaration of the formula and stamp duty was levied on them. The Pharmacy and Medicines Act of 1941 now makes it incumbent on the manufacturers to declare the formula, and stamp duty has been abolished. Control on the advertisement of proprietory medicines is effected through the Merchandise Marks Act of 1857. Under this Act the officers of a Government department or officials of local authorities or any other organisation of persons can prosecute for false description. The proprietory medicines which contain poisons are additionally controlled by the Pharmacy and Poisons Act of 1953 which enjoin a number of cautionary notices such as 'Poison—Caution' etc. to be affixed to the bottles for use. Additional control is supplied through the Weights and Measures Act.

Control by voluntary system is an outstanding feature in U.K. In 1930 the Proprietory Association of Great Britain, a trade group consisting of manufacturers of proprietory medicines, set up a code of standards for advertisement of their produce. The code was first published in 1936 and has been added to from time to time. The manufacturers have applied themselves to the maintenance of the highest possible standards regarding manufacture, labelling and advertisement of proprietory medicines sold to the public. The latest code includes the following:

(1) Members are required to produce details of the new products including its formula, claim, packaging, leaflet and copies of proposed advertisement.

(2) Members are to submit to the Association any innovation or alteration in the label as well as copies of advertisements to be issued to the Press, Television, Radio, or to be displayed by means of public posters or show-cards.

(3) Members are precluded from using descriptions or addresses which may lead the public to believe that the drugs are from official sources.

This code also prohibits any reference to a number of vague ailments like enlarged gland, diseases of the kidney, varicose vein, etc.

These steps have raised the standard of advertisement and labelling of medicines to a very high level.

In U.K., therefore, the manufacturer when marketing a new product is faced with two sets of control—official and unofficial. The legal control is always in the background. Prosecutions under the Act are few and far between. The voluntary control system has become well-established, whereas the control by the State is essentially monitory.

India

220. In 1937, Dr. G. C. Anderson, M.D., Secretary of the British Medical Association, in his report on his visit to India during 1936-37 reported that "no attempt is made to control the quality of drugs sold in India, with the result that the market in India is flooded with drugs and preparations of impure quality and defective strength and such products as vaccine and sera are freely sold without having been tested as to their quality. It is a well known fact that firms manufacture cheap and inferior especially for the Indian market with the result that local producers follow suit". In other words, at that point of time drugs imported into India were not of standard quality. About the practice of pharmacy, he reported lack of adequately qualified men and suggested training of pharmacists. He mentioned about the recommendations of the Drugs Enquiry Committee (1931) and recommended that a suitable carriculum and statutory control of the practice of pharmacy be ensured. The control through the existing laws like the Opium Act, Dangerous Drugs Act and Poisons Act, was considered ineffective, being only partial and covering only a few drugs.

Since then a number of Acts have been passed and today drug control in India is entirely statutory, partly Central and partly on a State basis. There is a Drug Controller for India, assisted by Assistant Controllers at the principal ports. He is principally concerned with the control of imports and in maintaining uniformity in Drug Control Administration in all the States. In addition, he advises the State Organisation through the Central Health Ministry and the State Drug Control Administration demi-officially. He is consulted for legislative matters. He is also the Head of the Central Drug Advisory Board. The Central Government have two Laboratories, one at Calcutta and the other is the Drug Research Institute at Kasauli.

The Provincial control is exercised by the Director of Health Services, who is the ex-officio Drug Controller. The State Government has a Provincial Drug Control Laboratory. Testing is also done at the laboratory of two private firms—Italab, and Briggs & Co. These have been approved by the Drug Controller.

In India the first control legislation was the Opium Act of 1878, which followed the recommendation of the Opium Commission. It seeks to control the manufacture of opium by making it a Government monopoly, and prohibits illegal cultivation of opium root (Papaver somnifera). This was followed by the Poisons Act (Act XII of 1919), which authorised the State Government to regulate possession and sale of poisons, while the control over import of poisons vested in the Central Government.

The Dangerous Drugs Act (Act II of 1930) was the next legislation, passed after ratification by India of the Geneva Convention (1925) for international control of trade in dangerous drugs and control of internal manufacture and sale of dangerous drugs defined under clause (f) of section 2 of the Act, to include coca leaf, hemp, opium and all manufactured drugs, which meant coca derivatives, medicinal hemp, opium derivatives and other narcotic substances which the Central Government might specify.

The Drugs Act (1940) is the next comprehensive legislation and has been fully dealt with later in this Chapter.

A Central Act, called the Drugs (Control) Act (Act XXVI of 1950), was enacted to control the sale, supply and distribution of drugs in Part C States. The comparable legislation in West Bengal was a State Act, the West Bengal Drugs (Control) Act (Act XXVI of 1950).

The last in the series is the Drugs and Magic Remedies (Objectionable Advertisement) Act (Act XXI of 1954).

3.2. HISTORY OF THE DRUGS ACT (1940)

221. For proper appreciation of the Drugs Act a critical review of the tendencies and opinion prevailing at the time of the enactment is necessary.

222. In 1927 in response to public demand for legislation for control of sale of imported drugs the Council of State resolved that the Government should take steps to enforce drug control.

223. In 1930 the Medical Council of Great Britain withdrew the recognition of Indian Medical degrees. This resulted in country-wide agitation. Leading Medical men and chemists of India, like late Dr. Sir Nilratan Sarkar, Dr. Sir P. C. Roy, Dr. Deshmukh, Dr. Mehta and Dr. Mudaliar launched a countrywide movement for boycott of British drugs and medical preparations. This in turn gave a fillip to the manufacture of drugs in India.

224. Apparently unnerved by the movement the Government of the day appointed a Committee under Col. R. N. Chopra. The Committee published its Report in 1930. But nothing was done to implement their recommendations at the time. In 1935 another resolution was passed in the Council of State calling the attention of the Government to the Chopra Report.

225. In 1937, Dr. Anderson, the Secretary of British Medical Association, toured India under the direction of the Association and submitted a report alleging that the market in India was flooded with imported drugs and preparations of impure quality and of defective strength. Lt.-Col. M. A. Rahaman, a member of the Central Legislature, during the debate on Drug Bill in July 1940, stated—"It was well known that firms in other countries manufactured cheap and impure drugs specially for India with the result that local producers followed suit." Finally in 1937, that is six years after the Chopra Report the Government came out with a Bill known as the Drugs Bill. The Bill was referred to a Select Committee. The Bill came up before the Lower House of the Indian Legislature in 1940.

226. The Drug Bill therefore, was not a straight forward result of recognition of spurious drugs in the market and was initially directed against imported drugs which according to the industrial Commission Report in 1918 amounted to Rs. 125 lakhs and was of the order of Rs. 250 lakhs, in 1940. Considering the value of the rupee at this time, the amount spent on the import of drugs was considerable even by standard of modern consumption from the point of view of price.

The Act was primarily directed against imported drugs.

227. We have indicated under separate chapter, gross deliberate adulteration of foreign drugs noted by Dr. Anderson, Secretary of British Medical Association, in 1937. The Indian manufacturers and Indian drugs were included in the list at the Select Committee stage. Therefore, the Act has undue emphasis on import. Chapter 3 which deals with imported drugs has eight sections out of a total of 37. The operative part of the Act is confusing and statutory control was loose at the initial stage. The rules under sections 6(2), 12 and 33 of the Drugs Act, 1940, were notified only on 21st of December, 1945, i.e., 5 years after the enactment of the Act. Presumably the Government of the day was busy dealing with the affairs of the second World War and therefore, very little attention was paid to it. It is during this period that firms manufacturing spurious and sub-standard drugs sprank up like mushrooms. Everything was in short supply and specialy medicines which were being consumed by the armed forces. No one knew how many lives perished because of administration of spurious drugs. This period synchronised with the discovery of new drugs which were very high priced. This high price of these drugs encouraged malpractices. Apparently the Act and the rules were framed in a hurry as will be seen from numerous amendments, the first of the series being Drug Amendment Act of 1955 which amended:—

(1) The definition of the Drugs vide Clause (b) of Section 3.

(2) Defined manufacture vide Clause (f) of Section 3.

(3) Added three representatives to the Pharmacy Council vide Clause IX of sub-section 2 of Section 5.

(4) Authorised the Central Government to make Rules prescribing the functions of the Central Drug Laboratory and matters connected therewith.

(5) Prohibited import of patent and proprietory medicines unless the label contained the true formula or list of ingredients in it, vide Clause (d) of Section 10.

(6) Authorised the Collector of Customs to impound packages suspected to contain drugs prohibited under the chapter, vide sub-section 2 of Section 11.

(7) Specified disease and ailments which an imported drug may not purport or claim to prevent, cure or mitigate, vide Clause (d) of sub-section 2 of section 12.

(8) Authorised the Central Government after consulting the Drug Technical Advisory Board to amend any schedule vide sub-section 2 of section 16.

(9) Prohibited the manufacture, sale or stock or exhibition for sale or distribution of patent or proprietory medicines unless the label displays in the prescribed manner the drug formula or the list of ingredients.

(10) Section 22 amended the powers of the Inspectors.

(11) Section 28 specified the penalties for giving false warranty or misuse of warranty.

(12) Chapter V which contains miscellaneous provisions was added by the Drug Amendment Act of 1955 as also the Schedules.

228. The Second proviso to Section 10 of the Act reads "Provided further that the Central Government may, after consulting the Board, by notification in the official Gazette, permit, subject to any condition specified in the Notification the import of any drug or class or drugs not being of standard quality." The Commission was unable to ascertain the exact reasons for the incorporation of the provision in the Act. They recognise that perhaps advantage might have been taken by some importers of this provision for importing substandard drugs for one purpose and actually utilising them for some other. The Commission so far has not come across any legislation of this nature in any other country.

3.3 CRITICISM OF DRUG ACT AND SUGGESTIONS

229. While examining the adequacy of existing laws the Commission was faced with definitions which appear to be confusing.

230. The term "Drug" had not been defined in any legislation in India prior to the Drugs Act (1940). It was defined in clause B of section 3, to include "(i) all medicines for internal and external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals other than medicines and substances exclusively used or prepared for use in accordance with the Ayurvedic or Unani systems of medicines and (ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermins or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the official Gazette."

231. As a working definition, it is difficult to distinguish between "medicines" and "substances". The term "substance" is not defined in the General Clauses Act. In the Oxford Dictionary "substance" is defined as a "particular kind of matter," also a "material as opposed to form." It has also been defined as "category" that is substratum with cognizable properties or quantities or attributes or incidents of things conceived as inherent or affecting the essential nature of underlying phenomena. It is presumed that the term "substance" has been used in the first sense, i.e., "particular kind of matter". "Medicine" is defined in the Oxford Dictionary and in the New Gould Medical Dictionary (Published by McGraw 2nd Edition) as "substance taken internally" and "substance used for treating diseases", respectively.

232. Some medical practitioners, including eminent physicians and surgeons are put off by comprehensive definitions. Drug, according to Goodman and Gilman's [Pharmacological Basis of Therapeutic' (2nd Edn.) --a Macmillan publication] is a chemical agent which affects living protoplasm. According to them, few substances can escape inclusion in this definition. The amended definition is comprehensive and includes reagents used in the laboratory. For the physicians drug has a restricted meaning because he is concerned with its action in the therapy of diseases.

233. It is not for the Commission to suggest the exact terms for redefining "drug" to obviate the difficulties pointed out. But it should be readily comprehensible both to the laymen and physicians. The Commission would recommend to the appropriate authority the acceptance of definition of Drug given at page 14 of World Health Organisation Technical Report No. 138 published by WHO from Geneva (1957). The WHO study group recognised that the definitions in various countries were not rigid and that in some countries a term defined in a Statute is again defined differently in

a Regulation. They recognised that "Drug" and "Pharmaceutical preparation" are often defined synonymously. Most of the definitions were weak. They, therefore, recommended the following definition "a drug (or pharmaceutical preparation) is any substance or mixture of substances manufactured, sold, offered for sale for treatment of disease."

234. A Drug of "standard quality" is defined to mean that the drug complies with the standard set out in the Schedule to the Drugs Act. So we have two categories of drugs one, "standard" the antithesis of which is "sub-standard," and the other is "misbranded". The term "standard" is with reference to quality. Branding has reference to display.

235. The Commission had occasions to use the term "adulterated drugs." The new amendment has defined "adulterated drug" in Section 9(B) as under:

(a) if it consists in whole or in part of filthy and putrid or decomposed substances, or

(b) if it has been prepared, packed or stored under insanitary condition whereby it may have been contaminated with filth or whereby it may have been injurious to health, or

(c) if its container is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health, or

(d) if it is clear that it contains for the purpose of colouring only a colour other than as prescribed, or

(e) if any substance has been mixed or packed herewith so as to reduce its quality or strength or substitute wholly or in part thereof.

236. The Commission was in some difficulty in following the definition and understanding the meaning of some of the words in the amended Act.

237. The Commission would like to use the word "adulterated" to mean that part of the ingredients of the drug has been taken out or substituted by products other than those specified, and "spurious" to mean drugs which do not contain any of the specified ingredients.

238. Entry 4 in the Schedule to the Act says—for drugs, the standard of identity, purity, strength, specified for the time being in the British Pharmacopoeia or British Pharmaceutical Codex or in other prescribed pharmacopoeia, or adopted by the permanent Commission on Biological Standardisation of the World Health Organisation, are adequate. This gives a wide scope to the unscrupulous drug manufacturers to refer to different editions and to the Pharmacopoeia of different countries, causing confusion. Indian Pharmacopoeia has been published in 1954. It is suggested that the schedule should be amended and referred to I.P. only with such modification as may be incorporated therein from time to time.

239. Copies of the Biological Standardisation of WHO are not readily available in India and therefore attempt should be made to publish this locally or to make adequate copies available.

240. There are other minor lacunae specially in the Rules. Generally speaking the Commission would suggest that the number of forms should be reduced and Schedule F under Rule 78 and Part X should be rationalised. In Schedule F a number of monographs have been reproduced which appear to be redundant. To take an example, Part 6 refers to insulin. This is given in details in the Indian Pharmacopoeia as well as in the British Pharmacopoeia (1958). Unless it is the intention of the Government to make details

available to the readers without their buying a copy of Pharmacopoeia, there does not appear to be any need for including such matters in the Rules.

241. While on the subject of enforcement and adequacy of Laws, the Commission had to refer frequently to the Pharmacopoeia. India has now her own Pharmacopoeia compiled by the Parmanent Indian Pharmacopoeial Committee under Notification No. F-1148D.F., dated 23rd November 1948. We would recommend that the I.P. be periodically revised like the British Pharmacopoeia. The B.P. Commission have been revising their edition every five years from 1932 onwards.

242. A peculiar feature in the Drugs Act is the second proviso to section 10. The Central Government is authorised, in consultation with the Drugs Technical Advisory Board, to allow import of Drugs which are not of standard quality. If there are considerations which permit the import of sub-standard drugs, surely the indigenous manufacturers could ask for similar consideration. One view is that standards specified in some Pharmacopoeia are so very rigorous that it may not be necessary to insist on compliance with the specifications therein. This may be true but there is no doubt that this will defeat the fundamentals of Drug Control, namely that medicines must conform to the standards specified.

243. A part of the Schedule M to the Drugs Rule is mandatory while the rest is recommendatory. The consequence of violation of the rules is not clearly stated either in the rules or in the Act itself. This lacunae in the rules could be taken advantage of by unscrupulous manufacturers. It therefore requires examination and further thought by the Government to put matters right by including in the rules only such matters as are considered mandatory.

244. In addition to the amendments to the Drugs Act suggested in the different parts of the Report the recommendations made by the Pharmaceutical Enquiry Committee in their report (1954) were considered and the Commission generally agrees with the recommendations made therein. Some of the outstanding points are summarised below with comments whenever necessary.

245. Law should be enacted so that no proprietary preparation could be marketed without the full formula being disclosed and displayed.

246. The suggestion that trading in the spurious and sub-standard drugs should be made a cognizable offence is open to criticism as any one dissatisfied with the dispensing by any firm may lodge a complaint at a police-station and cause harassment. The Commission would recommend that prosecution of concerns should be subject to sanction from a fairly high ranking officer. The members of the public aggrieved may send a written complaint to the Assistant Controller or Director who after a preliminary enquiry will authorise the police to take cognizance if necessary. The suggestion that the offenders' names and addresses should be compulsorily given publicity is commended. Under the existing provision of the act the court has powers to order such publicity to be given and this power should be invoked whenever found necessary. Under the existing Act, there is no provision for convicting a man for mere possession of a spurious drug. The Pharmaceutical Enquiry Committee felt, and the Commission agrees that possession of spurious drugs in whatever form by dealers should be an offence as this would be a deterrent.

247. Once the Pharmaceutists and the canvassers know that they are liable to be prosecuted and probably jailed, they will exercise due caution in purchasing or vending medicines from questionable sources. This circumspection is at present surely lacking.

248. The Commission does not agree with the recommendations of Pharmaceutical Enquiry Committee in as much present procedure of seeking permission from the District Magistrate or the Chief Presidency Magistrate should be deleted. It is necessary to provide for stringent measures for operation of law but it is equally necessary that the law is not operated in an oppressive manner by persons who lack experience.

249. The Commission agrees with the suggestion of the Committee that no license for manufacture of pharmaceuticals should be given unless all the minimum requirements are fulfilled.

250. The difficulty has been that a large number of factories were in existence before the Drugs Acts came into operation. An equally large number of factories sprang up before the Drugs Rules came into operation. A large number of small factories grew up after partition, mostly manned by chemists and others from East Bengal. Although the Drug Rules under the Drugs Act were promulgated in 1954, no action was taken to enforce the provisions of these Rules in West Bengal till 1957. It is not possible to carry out detailed inspection of the existing premises and straightway close down the smaller ones who do not conform to the standards specified in the Drugs Act and the Schedule. Moreover, if these units are closed abruptly, a large number of persons would be thrown out of employment and the investment of the middle-class Bengalees would be lost. The number of loan Licenses is 15 (fifteen). Utilisation of the existing surplus manufacturing capacity of the existing drug manufacturing concerns under loan Licences by these small non-viable units is one of the suggested solutions of this problem.

251. The Commission has referred in the body of its recommendation to the necessity for stricter control on the quality of drugs. There should be legislation laying down the composition of raw materials. Such legislation should also provide for licensing of dealers in raw materials, who will have to maintain correct records showing imports and sale of material, the names of the parties to whom materials are sold, showing the quantity and price charged therein. The manufacturers who obtain raw materials directly from their own plantations or other indigenous sources should also be similarly licensed.

252. The provisions regarding containers should be made more vigorous and statutory. It appeared to the Commission that the system of sealing containers is fairly satisfactory. The metal caps are sealed by a special process. It should be possible to devise opening of the caps in such a manner that the head of the glass container or metal container is broken as the seal is torn. The latest innovation is strip packing for tablets and similar preparations. Government should specify under the Rules the exact forms in which various preparations should be packed and sealed.

253. For parenterals, specially water for injection, there should be statutory provision that the glass ampoules should conform to the standard and that each glass ampoule shall bear on its outer surface the batch number, the date of manufacture and a note that the product is pyrogen-free. This should be by an impression on the glass. These recommendations are on the basis of suggestions by eminent medical practitioners who have faced practical difficulties in the matter.

254. For sutures and ligatures, similar safeguard should be provided. Fortunately, however, the Commission has not come across any case of adulteration in these items. There should be provision in the Act for their safety.

255. Specification of the glass used for storing materials, both for manufacture and sale, should be made in the Schedule. Generally cork was used as a stopper. This has to a great extent been replaced by rubber stoppers. Some of the rubbers are synthetic materials, which is not free from dangers of disintegration or reaction with chemicals producing noxious substances. Therefore, the specification of the stoppers should also be detailed carefully.

256. To sum up, the entire Drugs Act and the Rules should be subjected to immediate revision by a body of experts who will study similar legislation in other countries of the world and submit a draft bill and Rules to the appropriate Ministry for consideration.

257. In deciding the nature of the legislation, firm decision will have to be taken regarding the responsibility for administration of the Drugs Act. If the administration of this act is to be decentralised as in the United Kingdom, it should be split into two parts. One Act for controlling imports to be Centrally administered, the other for controlling manufacture, sal and distribution of drugs to be administered by the States. If, on the other hand, the drug administration is Centralised, even then there should be two different legislations, one for control of imports, licensing, etc., and the other for control of manufacture, sale and distribution.

258. The Pharmaceutical Enquiry Committee has recommended that the Drug Control Administration should be Centralised. The Commission does not agree with this. India is a country of vast distances and varying conditions. There is no chance of distances being reduced by air travel within the foreseable future. As administration of justice is the responsibility of the State Government, enforcement of the Drug Control measures should be the responsibility of the States. The Indian Penal Code is a Central Act, but it is administered by the States. What is really needed is a separate Drug Control Administration which will operate a more easily intelligible system.

3.4. PHARMACY ACT

259. The practice of pharmacy is as old as the practice of medicine Although the Bengal Medical Act was passed in 1914 and section 17 of the Act specified the qualifications for registration, it was not till 1948 that the Pharmacy Act was passed. The Chopra Committee's recommendations which formed the basis for the Drug Act specifically suggested that the Pharmacy Act should precede the Drug Act. But, the order was however reversed.

260. The Pharmacy Act provides for constitution of a State Pharmacy Council (section 19). It also provides for inter-State agreement for constitution of a joint Council.

261. Chapter 4 deals with maintenance of a Register and the qualifications for entry in the first register (section 31). Section 32 deals with the qualifications for subsequent registration which are fairly rigorous, namely that he must be a Registered Pharmacist in another State or one possessing qualifications approved under section 14. However, for the benefit of the displaced persons, section 32A was inserted by Act, XXIV of 1959.

262. This entitled a displaced person who prior to 4th March 1948 wa in the pharmaceutical profession or business, to have his name registered as a Pharmacist irrespective of his technical qualifications.

263. Section 42 prohibits dispensing of drugs by unregistered Pharmacist. The Pharmacy Act though initially enacted with the intention o

operating it rigorously has in course of time and because of laxity in administration become almost a dead letter. The miserable condition of the Pharmacist was first brought to light in the Drug Enquiry Committee's Report (1931) followed by the Bhore Committee's Report (1938) which recorded that there had been no marked improvement in the practice of Pharmacy. The Bhore Committee recommended statutory compulsion for dispensing of drugs by qualified pharmacists.

264. The Commission wishes to place on record an anomaly. Whereas the Drugs Act and Rules permit a person with four years' experience in dispensing to be called a qualified person, the Pharmacy Act of 1948 says that experience must be for 5 years before he can be registered as a qualified pharmacist. This should be clarified.

265. The Commission recommends that the practice of pharmacy should be rationalised by keeping out or replacing over 10,000 pharmacists registered under section 31(d). According to the Register maintained by the West Bengal Pharmacy Council, constituted under Government Notification No. 33953/5P-13/59, dated 29th April 1959, the total number of registered Pharmacists during 1st April 1958 to 31st March 1961 was 12,174, of this number 3,422 were removed due to non-payment of fees. The number registered under section 31(A) that is degree or diploma holder in pharmacy or pharmaceutical chemistry or chemistry is less than 150. There are 42 persons who are qualified under sub-section (B), that is, they were graduates. This includes even graduates in Humanities. However registration under section 31(d) has since been stopped. There are 2,000 registered pharmacists under section 31(C), that is, they are diplomaed and trained. These facts disclose a sad state of affairs. According to the statistics available, the number of pharmacies in and around Calcutta is nearly 6,000 (vide map at the end of this report). If these have to be manned by qualified pharmacists, we would need to have immediately another 4,000 pharmacists.

266. The Commission would recommend that the State Government should take the matter up immediately and arrange for training of more students in Pharmacy. A start has been made at Jadavpur with 25 seats for B. Pharm. course, and at Jalpaiguri with an annual intake of 50 students only for Dip. Pharm. course. But this is not considered adequate. The Commission learns that even these 50 seats are not fully filled up annually, the reasons for this being the low scale of pay of qualified pharmacists (Rs. 125 to Rs. 250). The Commision would recommend that there should be more such institutes distributed throughout the State and that the pay scale of pharmacists should be suitably enhanced to attract more and better qualified candidates.

267. The Commission was happy to note that the West Bengal Pharmacy Council has appended a Code of Ethics for Pharmacists. This is given in Part III of the Report.*

3.5. THE WEST BENGAL DRUGS (CONTROL) ACT, 1950

268. The West Bengal Drugs (Control) Act was passed in 1950. The Act seeks to control the sale, supply and distribution of drugs. The provisions of this Act are in addition to the existing laws on the subject. By virtue of power conferred under section 4 of the Act, the State Government could fix by a notification in official gazette the maximum prices and rates and the maximum quantity to be possessed by a dealer, as well as the quantity that can be sold in any one transaction but unfortunately no such

*Part III of the Report has not been received.

notification appears to have been promulgated by Government. The Commission would invite the attention of Government to the matter and recommend that suitable action be taken to implement the provisions of the Drug Control Act of 1950.

269. In the matter of costing of drugs there are two views. One view is that if the issue of free samples, which is at present tax free up to 5 per cent., is disallowed, there will be a proportionate reduction in the cost of medicine to the ultimate consumer. It is possible that the total saving to the community may be considerable. The other view is that of the manufacturers who maintain that this 5 per cent of free samples is the best form of advertisement and publicity for their products. With the increase in sale their cost will come down as their overhead will have been covered.

270. There may be a harmful aspect of distributing samples to all and sundry medical men. These samples may not all be utilised by them and some of these may find their way into the Bazzar through the domestics and others.

3.6. DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT, 1954

271. The Drug Council of the Pan American Health Organisation voiced its opinion on unification of regulations with particular reference to advertisement of medicaments. The Council stated that the following general principles should be followed in controlling advertisements:

1. Information should remain free, but advertisements to the laymen should be subject to control in respect of such medicaments as are habit forming or may harm the system or may be misused.
2. The authorities should have power to take drastic action against persons who advertise to mislead the public or induce the public to run the risk of health.
3. Action should be repressive, but it is realised that it cannot be prevented.

272. This is exactly what is happening in West Bengal today. Electric lamp posts and such other places are plastered with advertisements which offend the provisions of the Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 (XXI of 1954.) Some of the remedies advertised are really formulations for effecting abortion, but they are advertised as remedies for correction of irregular menstruation. The formulations contain Santonin. Assay of Santonin is difficult.

273. Provisions for pharmaceutical advertising are included in special legislations in countries like France, Federal Republic of Germany, Greece, Ireland, Peru, Poland and Spain.

274. In France, there is a distinction between technical advertising and public advertising. Higher Pharmaceutical Council, in 1947, emphasised on on the control of advertisement by stating "Medical advertising must be truthful and accurate and to this end should be subject to ethical control under the Ministry of Public Health by body composed of medical practitioners and pharmacists representing their respective Associations." (J. Blockringer: Bulletine 1960, No. 3: Page 58.)

275. In U. K. the British Pharmaceutical industry has established their own code for sales promotion practice for medical specialities, which specify the practice of technical advertising.

276. U.S.A.—In the United States, federal control is through the Food Drug and Cosmetic Act, the Federal Trade Commission Act and the Postal Fraud Statutes. State control is exercised through the old Federal Food, Drug and Cosmetic Act, 1906, revised in 1938. According to the interpretation given by the American Court of law labels or other written printed or graphic matter includes what is stated on the label and as such is an advertisement. Failure to specify the details of use and purpose renders a drug misbranded. Similarly if the threapeutic indications are inapplicable to the disease referred to in the advertising copy or on the label, the drug is misbranded. Thus indirectly the American Act controls false advertisement: The Federal Trade Commission Act controls all advertising media except a label. Unfair or deceptive practice of disseminating false advertisement inducing public to purchase food, drugs or cosmetics is prohibited. Although the Act specifically states that advertisement does not include labelling, Courts have held that false labels come under the purview of the Act. In a sense the Federal Trade Commission Act is a comprehensive Act for controlling advertisement in all its different forms.

The Postal Fraud Statute of America prohibits "any scheme or device for obtaining money or property of any kind through or by false or fraudulent representation or promise."

While the Federal Trade Commission Act covers cases of misleading advertisement in general, the Postal Fraud Statute are restricted to persons acting with mens rea. As in all advanced countries, the Americans have associations of advertising agencies who have a code for their members. There is a National Bureau to maintain standard but business firms also exercise control. (See Page 13—Practice you should know about advertising, New York.) In addition Drug Advertisement is subject to voluntary control by the Pharmaceutical Manufacturing Association. This Association prohibits advertisements of claims unsupported by authoritative scrutiny.

The American Medical Association have launched a programme for educating the public and they discourage deceptive and misleading advertisements and use of superlatives. One of the evils of advertisement is self-medication. In the U.S.A. large quantities of medicine with no therapeutic value are used by urban families, who spend large amount of money for these drugs. The American Medical Association are discouraging this. The Commission is in entire agreement with the American approach to the subject.

277. Japan.—The only control on pharmaceutical advertising is section 34 of the Pharmaceutical Affairs Law, 1948, which prohibits advertising and publication of false statements and exaggerated assertions. It also prohibits the use of any testimonials.

278. Italy.—In Italy the Health Law of 1934 enjoins the prior permission of the Ministry of Health in all advertisements through the press or any other media of all pharmaceutical products including prophylactics and medico-surgical appliances. The Ministry of Public Health is assisted by a Committee of Experts appointed by the Minister. A drug must be registered under Regulation of 1927. Registration is refused in respect of drugs:

(a) in which the ingredients are incompatible;

(b) which are misbranded in the American sense;

(c) which possess ingredients which might cause abortion;

(d) which claim to cure Cancer, Pulmonary Tuberculosis and such other ailments decreed by the Ministry of Public Health in consultation with the Supreme Public Health Council.

The law has prohibited advertisements in Baby Foods and dietetic products. Section 10 of the Royal Decree, dated 30th May 1953, prohibits the advertisement of preventive properties of a product which is exaggerated or any display which may lead one to believe that it has been recommended by a physician. The sale of samples of Baby Food or dietetic products for publicity purpose is also prohibited.

279. Federal Republic of Germany.—Drug advertisement is controlled by the Ordinance of 29th September 1941. It controls both drugs for human beings and animals. Misleading advertisement is prohibited. Sales promotion by lectures or door-to-door visit is prohibited. Advertisement is to be addressed to Physicians, Veterinary Surgeons, Pharmacists and persons engaged in the trade and not to the public. Letters of thanks and similar other valedictory statements cannot be advertised.

280. Turkey.—In Turkey the regulations are extremely rigorous and all advertisements must pass through the Ministry of Health and Social Service.

281. An analysis of the existing legislations in the various countries indicate that one or some of the following are statutorily prohibited:

(1) Self-medication of specified drugs;

(2) Advocating self-medication;

(3) Creating panic;

(4) Recommending a remedy as infallible or possessing magic power;

(5) Tendering free information for self-administration;

(6) Issue of samples to the public;

(7) Offering money back if treatment is unsuccessful;

(8) Displaying medical certificates or testimonials;

(9) Publishing letters of thanks;

(10) Describing symptoms of certain diseases.

282. The Indian Act prohibits advertisement of certain drugs for treatment of certain diseases which have been specified in the Rules. It also prohibits misleading advertisement relating to drugs.

283. Technical advertising in India is not subject to any restriction, except that it has to be communicated to the registered medical practitioners or wholesale or retail chemists through confidential channel. In a vast country like ours where very few people read any printed material and drug factories thrive and multiply, education of the public in this matter is necessary. Unfortunately, neither the All-India Radio nor the Rural Publicity Units of the State Government pay any attention to this vital question.

284. Penalties specified in Section 7 of the Act, however, is light and in the case of first conviction the maximum penalty is 6 months imprisonment or fine or both.

285. The Commission would recommend that penalty should be more severe and in line with Section 27 of the Drugs Act which specifies that punishment shall not be less than one year.

3.7. MAHARASHTRA DRUG CONTROL ADMINISTRATION

286. The Commission is of the opinion that the Drugs Control Administration in Maharashtra is comprehensive and with suitable alterations would be helpful in setting up the Drug Control Administration in West Bengal.

287. The Drug industry in Maharashtra meets nearly 70 per cent. of the drug requirements of the whole country. There are over 1,000 manufacturers (licensed premises), including some foreign firms such as Ciba and Sandoz of Switzerland, Merck Sharp & Dhome of U.S.A., Glaxo Laboratories of U.K., etc. The capital invested so far is about 27 crores, and the industry employs about 20,000 workers.

288. The Maharashtra Drugs Control Administration not only acts in a preventive capacity, but also performs important positive functions, viz., tendering advice to the manufacturing units in order that they may develop on sound lines. Expert advice is also given on planning, layout and quality control to entrepreneurs who are fresh in the field. There are two wings of the control organisation:

(1) Administration, and

(2) Testing.

289. *Administration Wing.*—In addition to routine duties it performs other functions, such as:—

(1) Evaluation of the reports received from Government Analyst and recommendations for regulatory and other necessary actions.

(2) Tendering technical advice, when necessary, to the manufacturers for improvement of layout equipment, etc.

(3) Co-operation with officials and enforcement of the provisions of the Poisons Act, the Dangerous Drugs Act, the Bombay Prohibition Act and the Bombay Drugs (Control) Act.

(4) Convening meetings of trade and professional associations and the Maharashtra State Pharmacy Council constituted under the Pharmacy Act (1948.)

The set-up of the Administrative Wing under the Department of Urban and Public Health is given in Annexure "A."

290. *Testing Wing.*—This is housed at present in the Haffkine Institute, under an Assistant Director (Pharmacology), and is engaged in developing new methods of testing of drugs for effective enforcement. The details of this Section are given below:

Functions

(a) Analysing samples sent by the Inspectors.

(b) Improving analytical methods suitable to Indian conditions for speedier disposal of samples sent for test.

(c) Research and development of new analytical methods for dealing with novel methods of violation of Drug Control Orders.

Set-up

The details of the staff of the Drug Testing laborartory are as under:

	Name of the post.	No. of posts.
1.	Assistant Director, I/C Department of Pharmacology and Government Analyst.	One
2.	Senior Scientific Officer, Class I, and Government Analyst ..	One.
3.	Senior Scientific Officer, Class II, (Pharmaceutical Chemistry), and Government Analyst.	One.
4.	Senior Scientific Officer, Class II (Biochemistry), and Government Analyst.	One.
5.	Senior Scientific Officer, Class II (Pharmacology)	One.
6.	Junior Technical Assistant	Two.
7.	Laboratory Assistant	Six.
8.	Junior Scientific Officer	Eight.
9.	Senior Technical Assistant	Thirteen.

291. The Maharashtra Government are said to be considering a proposal for a separate Drug Control Laboratory. The Administrative offices and Laboratory are to be housed in an independent building, 20,000 square yards of land would be acquired for that purpose.

Intelligence Section

292. This Section, directly under the Director:—

(i) investigates into offences under the Drugs Act,

(ii) exercises running check on manufacture by inspection of manufacturing units, and

(iii) exercises monitorial control over sales for the purpose of—

(a) preventing sale of spurious and adulterated drugs,

(b) ensuring that the drugs sold are of requisite potency and are not sub-standard.

According to the information furnished, this section detected a large number of cases of manufacture and sale of adulterated and spurious drugs including Penicillin, Chloramphenicol, Streptomycin, Sulphadiazine, M.B. 693, Irgapyrin, Waterbury's Compound, Super—D Cod Liver Oil, Liver Extract Injection, Milk of Magnesia, Vicks Vaporub, Woodward's Gripe Water, Dongre's Balamrit and Tasteless Quinks.

Prosecution was successful in most of the cases.

The staff employed consists of—

(1) Senior Drug Inspector—One.

(2) Junior Drug Inspector—Two.

(3) Watchers—Eleven.

293. The State of Maharashtra recognised the necessity for expeditious police assistance to the officers of Drug Control Administration, both for detection as well as for investigation. A special police staff, branch of the

Bombay Criminal Investigation Department, called the Crime Branch (I), C.I.D., Drugs Control, has been set up with—

(1) Inspector of Police—One.

(2) Sub-Inspectors of Police—Two.

(3) Head Constables—Two.

(4) Constables—Eleven.

Manufacture

294. This is subject to rigorous inspection, control and licensing. Site of the plants, technical qualification of the personnel, methods of manufacture, and background of the entrepreneurs are thoroughly checked.

There are over 24,500 licenses for selling of drugs in the State. Licenses for them are issued by Assistant Directors of the different divisions. Licences for manfacture, however, are issued from Headquarters only, as almost all the manufacturing units are in Greater Bombay.

Control of Advertisement

295. There is a separate Section for enforcement of the provisions of the Drugs and Magic Remedies Act, headed by an Assistant Director and assisted by:—

(1) Senior Drug Inspector—One.

(2) Drug Inspector—One.

(3) Examiners for checking advertisement in different languages—Six.

It is claimed that undesirable advertisement has been checked to a large extent. This Section checks over one lakh advertisements per annum in newspapers, magazines and journals and takes appropriate action against delinquents.

Import Control Branch

296. The policy for import of raw materials, equipment and machinery for the industry is controlled by the appropriate Ministry of Government of India. The responsibility for granting Essentiality Certificates to the small scale pharmaceutical units has been transferred to the Drug Control Directorate from October 1961.

The Directorate reviews the following before issue of Essentiality Certificates:

(a) Whether the entrepreneur has the capacity of equipments for processing the particular drug from the raw state, and if the drug is necessary in the interest of the country;

(b) Whether the basic raw materials are readily available from indigenous sources;

(c) Whether there are any comparable indigenous drugs;

(d) Whether the application involves import of machinery, plant and equipment which are indigenously manufactured.

In 1962 the Drug Control Administration of Maharashtra issued Essentiality Certificates for 41 lakhs of rupees.

Narcotics Branch

297. There is prohibition in Maharashtra. It has resulted in the increase of sale of illicit liquors in the form of tinctures and spirits causing hazards to health.

A Board of experts has been set up under the Bombay Prohibition Act. The Secretary of the Board is under the administrative control of the Director of Drug Control Administration and advises Government on problems connected with spirituous preparations. The Drug Controller is a member of the Board.

Price Control

298. The Drugs (Display of Prices) Order, 1962, was promulgated under the Defence of India Rules. The State Government has set up a Drug Prices Vigilance Committee under the Ministry of Civil Supplies, of which the Director of Drug Control Administration, is one of the Members.

299. The particular function of this Committee is to keep a continuous vigil over the price of drugs. They collect information through secret agents and prosecute the offenders.

The Maharashtra Drug Control Administration has given the following priority in their work:

(1) Problems involving hazards to health;

(2) Adulterated Drugs;

(3) Sub-standard Drugs;

(4) Other similar violations.

300. The present practice is that deliberate manufacture and sale of spurious or adulterated drugs come under penal action in the form of prosecution. In other cases unless there is mens rea punitive measures like suspension of licence or destruction of sub-standard drugs are resorted to. The offenders are then educated to behave and asked to manufacture according to directions given by the Administration.

Financial Aspects

301. Maharashtra Government placed at the disposal of the Drug Control Administration the following grants:

		Rs.
1961-62	...	5,47,457
1962-63	...	6,72,350
1963-64	...	7,53,972

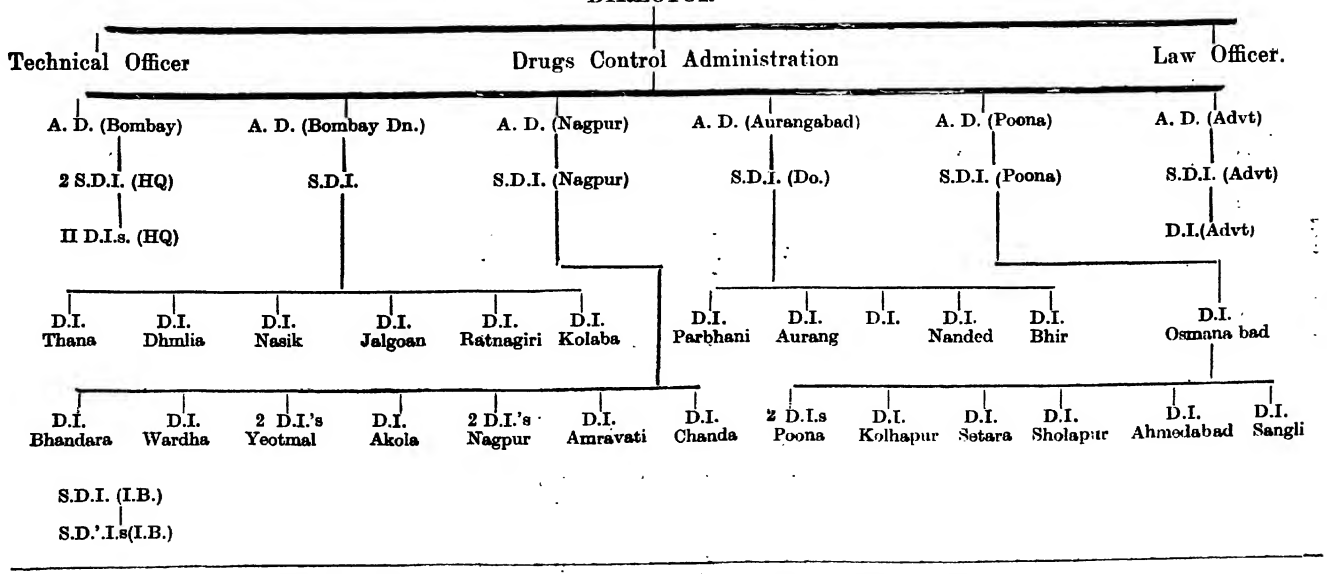
Against this, the receipts of the Administration by way of Licence Fees were:

		Rs.
1961-62	...	2,65,865 (approximately)
1962-63	...	3,98,680

The detaills of pay-scales and allowances of the different categories of officers and ministerial staff working under Maharashtra Drug Control Administration are shown in Annexure "B."

ANNEXURE "A"

Chart showing distribution of officers of Drugs Control Administration in Maharashtra State



H.Q.=Headquarters

A.D.=Assistant Director

S.D.I.=Senior Drugs Inspector

D.I.=Drugs Inspector

I.B.=Intelligence Branch.

Advt.=Advertisements Control Section

Dn.=Division.

13 Posts of Inspectors are vacant.

ANNEXURE "B"

Details of remuneration of officers working under Drugs Control Administration of Maharashtra

	Designation.	Pay Scale.	Pay.	D.A.	C.L.A.	H.R.A.	C.A.
		Rs.	Rs.	Rs.	Rs.		Rs.
1.	Director ..	650—45—1,100 + Sp. Pay 100 P.M.	650 + Sp. Pay 100	85	75	15% of pay	150
2.	Assistant Director (Bombay).	450—500—25—650 —EB—25—800	450	70	50	15%	105
3.	Assistant Director (Advt.)	Ditto ..	450	70	50	15%	105
4.	Sr. Drugs Inspector (H. Q.)	300—350—15—500 —EB—20—600	300	80	50	15%	95
5.	Sr. Drugs Inspector (Advt.)	Ditto ..	300	80	50	15%	90
6.	Sr. Drugs Inspector (Bombay).	Ditto ..	300	80	50	15%	..
7.	Sr. Drugs Inspector (Intelligence Branch.)	Ditto .. Sp. Pay 75	300 + 75	80	50	15%	60
8.	Drugs Inspector (H.Q.) and (Advt)	200—220—15—400 —EB—20—440	200	80	50	15%	45
9.	Drugs Inspector (Intelligence Branch.)	Ditto .. Sp. Pay 50	200 +50	80	50	15%	45
0.	Law Officer ..	280—15—400—EB —20—500—25— —550	on deputation.				
1.	Technical Officer	500—25—650—EB —25—800	500	80	90	15%	..

3.8. DRUG CONTROL ORGANISATION IN WEST BENGAL AND RECOMMENDATIONS

302. The Drugs Act was passed in 1940 and the Drugs Rules were framed in 1947. It was in April 1947 that the then Surgeon-General was appointed the first Drug Controller for Bengal under the Act, assisted by Deputy Licensing Authority, vide Government Notification No. D/MED/37/47, dated 31st May 1947. With the Partition, the Drug Control administration became a sectional office of the Directorate of Health Services. This apparently was a stop-gap arrangement, but unfortunately it continued. Today the Drug Controller is the Director of Health Services (ex-officio), assisted by a Drug Licensing Officer (with no statutory function because he is not recognised as such by the Drugs Act) and 10 Drugs Inspectors.

303. The present Drug Licensing Officer, Dr. B. B. Sircar and his predecessor in office, Dr. B. B. Majumdar, admitted that they were aware that they had no statutory authority and that they had drawn the attention of Government to this matter on a number of occasions. At present there are 10 wholetime Inspectors for Calcutta. Subdivisional Health Officers act as ex-officio Drug Inspectors for their respective areas. They are usually preoccupied with heavy public health duties. They do not appear to have sufficient time for inspection work under the Drugs Act. In addition to enforcement of the Drug Control Rules and other statutory functions, the Inspectors have to—

(1) Enforce the provisions of the Drugs and Magic Remedies (Objectionable Advertisement) Act of 1954.

(2) Implement the Resolutions of Seventh Narcotic Conference of 1956 for manufacture and distribution of narcotics.

(3) Issue Essentiality Certificates for import of raw materials, plants and equipments for small scale pharmaceutical industries.

(4) Conduct research for procuring data for enforcement of anti-profiteering measures.

(5) Compile miscellaneous statistics.

(6) Enforce provisions of Poisons Act, Dangerous Drugs Act.

(7) Enquire into the affairs of the Ayurvedic practitioners.

(8) Investigate into proper use of insecticides.

(9) Perform various other miscellaneous duties that devolve on them from time to time.

304. Under rule 52 of the Drugs Rules, an Inspector has to inspect all premises licensed for manufacture of drugs at least twice a year. According to statistics available with the Commission there are over 250 manufacturing premises and over 5,000 selling units. The Pharmaceutical Enquiry Committee recommended one Inspector for 200 selling premises and one for each 100 manufacturing concerns. The Director of Health Services, West Bengal, in his letter No. D.L.A./IP-22/54/6691, dated 20th December 1954, agreed with the recommendation. According to this yardstick, there should be for Calcutta only at least 25 Inspectors for selling premises and two for the manufacturing units. The present staff is inadequate by any standard. The Commission would suggest to the State Government study of the organisational set-up of the Drug Control administration of Maharashtra State. Out of 10+1 posts only four belong to permanent cadre and seven are temporary. They have to perform very difficult and unpleasant duties. In course of their evidence before the Commission some of them stated that the fact that they were in temporary service always

weighed in their minds and they could not take strong line of action for fear of reprisal. The Commission is of the opinion that all the Inspectors should be made permanent.

305. The office accommodation is also inadequate. Ten Inspectors sit huddled in a room in the Mitra Buildings in Lyons Range. They have no separate room for consultations nor have they telephones. No funds are made available to them for collection of samples nor is there any suitable space for storage of the seized articles. Reference books or journals are not available for use by the Inspectors. They have no transport facilities. It is, therefore, not unlikely that they have at times to depend on the transport provided by the manufacturing concerns they are about to inspect. They are allowed to draw only Rs. 20 per month as travelling allowance, which the Commission considers totally inadequate.

306. Throughout his professional career a Drug Inspector should be continuously gaining experience, which would help him in understanding the quality and other properties of drugs and their usages. A basic knowledge of the science of Pharmacy is essential but there should be Refresher Courses. Until recently there was no arrangement for pharmaceutical training in West Bengal. However, the Jadavpur University has recently made a start with provision for 25 students. At present Pharmacists are drawn from graduates from the Banaras Hindu University. But even this is not sufficient for Inspector's job. The Inspectors must have a background for analytical control of substances and properties of materials, applied microbiology, pharmacognosy, use of highly specialised modern equipments in the laboratories, which they can acquire only as a graduate apprentice in a reputed manufacturing concern where they must work for two years.

307. The Drug Control organisation in West Bengal is not yet fully developed. It appears that the Inspectors, for no fault of their own have not been able to enforce the provisions of the existing Acts and Rules. The Commission would recommend that there should be a Register kept in each manufacturing and selling concern in which there should be columns for dates of inspection; defects found by the Inspectors should be entered in another column together with the recommendations made. There should be periodic inspection of these Registers by the Inspectors. If instructions are not carried out, these would be referred to the senior officers for prompt action.

308. The Drugs Rules, Schedule M, clearly specify that the area should be free from smoke and the premises should not be located near open drains. Bagmari, Narkeldanga, Manicktola areas have open drains choked with vegetation and with soot settling everywhere and it is here that the largest number of small organisations exist. This is obviously undesirable and either the area should be made more healthy or the concerns should be removed to a healthier place.

309. For the 256 manufacturing units and over 10,000 lincensed selling premises, of which 4,177 are in Calcutta and suburbs and 5,950 are in the districts, there should be, in the opinion of the Commission, at least 50 wholetime Inspectors. The Drug Controller should co-ordinate all work and be responsible to the administrative department. The Commission found that there was a feeling of frustration amongst the Inspectors due to their being in a closed service, in the scale of pay Rs. 275—650. This should be looked into by Government. It is further suggested that Inspectors should have two grades—Junior and Senior Inspectors—with adequate pay scale in each case. The number of posts of Senior and Junior

Inspectors are to be determined by Government according to the nature and volume of work. The work of the Inspectors should also be properly distributed. Junior Inspectors should be entrusted only with the work of inspection of selling premises. Senior Inspectors who have more experience should inspect manufacturing concerns.

310. From the evidence placed before the Commission it appeared that there have been a number of cases where gross delays in inspections have occurred. There are instances where no inspections have been made during a period of four years. Cases have also come to notice where, even after the expiry of licences, drugs have continued to be manufactured and the Drug Control Department did ultimately condone the offence or extended the time limit.

311. A case in point is quoted below. A particular concern was reputed to be "manufacturers of Biological, Chemical, Pharmaceutical, Ayurvedic and perfumery products." Their licence expired in September 1960. No papers were available to the Commission as to when and how this licence was actually granted or how the firm received the Essentiality Certificate and imported a large number of plants and equipments as well as raw materials. It appears that the concern ultimately decided in 1960 to go out of business. Notice of this was given to the Drug Control Department. The concern used to manufacture "tinctures and spirituous preparations". To be fair to them it must be said that they asked for destruction of such stock as was necessary (vide their letter, dated 21st November 1961, to the Drug Licensing Officer). The manufactured goods were in bonded laboratories. The business was actually closed down in January 1961.

312. It is interesting to note, however, that in the relevant Health Directorate file there is a reference that the premises of the particular concern was inspected on 30th January 1962. It is stated in the list that they had with them such medicines, as Liq. Morphine Hydrochlor, Liq. Strychnine Hydrochlor and about 30 bulk gallons of Tincture Aconite. All these are dangerous drugs and when the Health Directorate Drug Control establishment inspected the premises on 30th January 1962, the report merely stated "No sign of manufacturing of drugs was seen in the factory. It seems that they have closed their business." There was no indication as to whether any enquiry was made as to the end use of these drugs or plants or equipments or how the plant, and equipments were disposed of. On this report, the only order recorded was "take action immediately." This was dated 31st January 1962 and curiously this order was reendorsed three months later on 5th April 1962, which apparently shows that during the intervening period no action had been taken.

313. This case illustrates that it is not in the national interest to issue import licences to firms who are not really interested in the business. It also prevents genuine manufacturers from securing a part of import quota and the necessary foreign exchange.

314. There should be a Control Laboratory and an Intelligence cell headed by a senior police officer of the rank of an Assistant Commissioner of Police or Deputy Superintendent of Police on deputation as is done in Maharashtra. As in Maharashtra the establishment should also have a legal adviser attached to it, so that if and when a prosecution is started for offence under the Drugs Act or the Rules, prompt legal action could be taken.

315. Some medical witnesses have referred to the necessity of deterrent punishments. The Commission feels that the present provisions in the Drugs Act of imprisonment and fine are adequate and the remedy

lies not in increasing the statutory provision for punishment but in reorganising the prosecution branch of the Drug Control administration. In suitable cases the Directorate should consult the law officers of the State and engage counsels or senior prosecuting officers, as is done in criminal cases. As the Commission is envisaging a separate Drug Control Administration outside the control of the Director of Health Services, and officer of adequate technical qualification, sufficient seniority, integrity and adminstrative ability should be appointed as the Drug Controller. The Drug Control organisation in West Bengal is now a mere apology and appendage of the Health Directorate. Moreover, the approach to the problems has to be for its own sake and not incidental. The first requisite is to have a proper administrative structure which requires an adequate number of qualified Inspectors.

316. The Drug Rules were brought into force in 1945 but due to the paucity of Inspectors it could not be implemented as periodical inspection of the manufacturing premises was not at all possible. The Commission has not been able to understand why six-monthly inspection was provided for under the Rules when adequate number of Inspectors were not available. The Drug Control administration should have had at least one inspection in two years. The department should prescribe a detailed proforma for inspection which should be sent in advance to the various manufacturing units and companies. They should fill up the form and return the same to the office of the Inspector who could then visit the premises for inspection without notice.

317. The Commission was surprised in one of their visits to a manufacturing concern where in pressurised air-conditioned ampoule filling chamber laboratory assistants were wearing spotlessly clean masks and gloves, whilst Members of the Commission were allowed to walk in as they were in street clothes and dusty shoes.

318. This brings us to the question of requisite qualifications for an Inspector employed, as well as of those who do the "tests" in the manufacturing concerns. There is a paucity of technically qualified men. Instructions given should be clear, precise and to the point.

319. Court cases often demoralise officers who thereafter follow the path of least resistance. In some quarters it is believed that political and other forms of extraneous considerations weigh with them and as such interfere with their legitimate discharge of duties. The Government Inspectors were closely examined by the Commission on this issue and they were assured that their names would not be divulged. Although they stated that no such matter weighed with them in the course of their work, yet there was a feeling amongst them that they might lose their temporary job.

320. The Commission is of the opinion that Inspectors who have been in service for at least five years should be sent overseas for gaining experience. The Government should also consider the feasibility of bringing foreign experts to this country on three years' tax-free contract basis, on a salary commensurate with the salary in their country for training men in the Drug Inspectorate.

321. The Commission examined witnesses at length on the working of the Drug Control Organisation in West Bengal. Memoranda were addressed to the Commission by the Bengal Branch of the Indian Pharmaceutical Association and Dr. B. B. Majumdar, the previous Drug Licensing Officer of West Bengal.

These have been reproduced in Part III of the Report.*

*Part III of the Report has not b een printed.

322. The following appear to be the principal reasons for the present unsatisfactory state of affairs in the Drug Control organisation in West Bengal:

(1) Inadequate number of Inspectors and Office staff;

(2) Assigning of duties to Inspectors without considering his suitability for the assignment;

(3) Want of supervision of the work of the Inspectors;

(4) Lack of funds for collecting samples by Inspectors;

(5) Want of transport facilities for Inspectors;

(6) Want of space for storing samples, a library of reference books and journals, a telephone, and adequate office accommodation;

(7) Unattractive scale of pay and lack of initiative as the service is a closed one; and

(8) Want of well-equipped testing laboratory.

In addition, there has been no consistent licensing policy, nor Intelligence Cell and prosecution wing, and no arrangement for advising entrepreneurs or manufacturers on control of production and quality.

323. Officials connected with Drug Control organisation more or less recommended the following for immediate implementation:

(a) Appointment of a full-time Drug Controller for performance of the statutory functions under the Drugs Act, Opium Act, Poisons Act, Dangerous Drugs Act, Drugs and Magic Remedies (Objectionable Advertisements) Act, and control over the staff under Rule 50;

(b) The Drug Licensing Officer, who has at present no legal status, should be redesignated as the Assistant Drug Controller and vested with statutory powers under the Rules;

(c) Chief Medical Officers of Health, Subdivisional Health Officers, Assistant Chief Medical Officers of Health, should continue to function in the Districts as ex-officio Inspectors;

(d) As recommended by the Pharmaceutical Enquiry Committee (1953), not more than 100 manufacturing premises or 200 selling premises should be allotted to any one Inspector for inspection under Rules 51(1) and 52(2);

(e) An Intelligence Cell should be created;

(f) Adequate funds in the form of cash or impressed should be made available to the Inspectorate for collection of samples;

(g) Strong rooms for keeping samples and secret documents, refrigerators for storing delicate samples, motor vehicles for Inspectors to visit the factories and selling concerns, should be provided;

(h) The State Drug Control laboratories should be properly equipped.

324. Taking all factors into consideration, the Commission would recommend the following:

1. The Drug Control Administration should be under a full-time Drug Controller, assisted by an Assistant Controller, Senior Inspectors and Junior Inspectors;

2. The Chief Medical Officer of Health and the Subdivisional Health Officers should continue to be ex-officio Drug Inspectors. Periodical inspection reports should be sent by them to the Drug Controller and they should be paid adequate fees;

3. There should be one Senior Drug Inspector for inspection of eac 100 manufacturing concerns, and one Junior Drug Inspector fo the inspection of each 200 selling concerns;

4. Specialised and/or larger plants should be inspected by the Dru Controller or his Assistant;

5. There should be an Advisory Cell under the Drug Controller heade by another Assistant Drug Controller whose duties shall be t keep himself informed with the latest methods of manufactu and information about sources from which raw materials coul be obtained and also to recommend improvement of raw material intermediates, penultimates, plants, machinery and equipment;

6. There should be an Intelligence Cell headed by an Assistant Com missioner or Deputy Superintendent of Police on deputation assisted by technical staff, for vigilance in locating manufactu in premises where spurious drugs are manufactured and reportin malpractices including those under Drugs and Magic Remedie (Objectionable Advertisements) Act. The said police office should be on deputation for three to five years with a speci pay. Information would be passed on to Drug Controller direc for necessary action;

7. There should also be a law section headed by an expert lawyer;

8. The Drug Control Laboratory should be an independent unit. I due course there is likely to be need for branch laboratorie situated in different parts of Calcutta and the State; and

9. The present State Drug Control Laboratory should be reorganise as recommended separately.

3.9. STATE DRUG CONTROL LABORATORY

325. The Director of the Central Drug Laboratory was kind enough t furnish the following information to the Commission under h No. 9-23/63-Ad./8235, dated 1st January 1964:

(a) Central Drugs Laboratory has five technical sections, viz., (i) Pha maceutical Chemistry Section, (ii) Biochemistry Sectio (iii) Pharmacology Section, (iv) Bacteriology Section ar (v) Pharmacognosy Section.

(b) The staff strength is detailed below while the salary scales in eac category are those normally applicable to Central Governme Staff:

Class I (Gazetted)	...	6
Class II (Gazetted)	...	9
Class II (Non-gazetted)	...	5
Class III (Technical)	...	42
Class III (Ministerial)	...	13
Class IV	...	40
Total	...	115

(c) The laboratory maintains nearly complete range of specialised instruments and appliances which are required for analytical and research work in different technical sections.

(d) During 1962-63, a total of 3,456 samples have been tested in this laboratory.

(e) The sanctioned budget of this laboratory for the year 1963-64 is Rs. 4,87,700.

326. Analysis of the working of the Central Drug Control laboratory shows that it is run satisfactorily within the limits imposed by physical consideration and that the overall cost of analysis is Rs. 140 per unit. This in the opinion of the Commission is exorbitantly high and the Commission cannot commend to some of the manufacturers or the State Government to have the samples tested at the Central Drugs Laboratory. The charges at Kasauli are equally high.

Working of the State Drug Control Laboratory

327. A well-equipped and properly manned Drug Control Laboratory is sine qua non for effective drug control. The Commission were concerned to find that the present State Drug Control Laboratory is situated in the building of School of Tropical Medicine and is an apology for a laboratory. The laboratory was started in 1938 as a drug testing unit by Col. Chopra, the then Director of the School of Tropical Medicine. The laboratory was put on a permanent basis under Government Order No. 2377Medl., dated dated 23rd October 1940. The staff consisted of one Chemist, one Pharmacologist and one Biochemist, three Laboratory Assistants, one clerk and three sweepers in each of the above three sections. The Chemist, the Pharmacologist and the Biochemist were sent to the Central Drugs Laboratory for specialised training in analysis and standardisation for three years. The laboratory was then under the Director, School of Tropical Medicine, and has to function as a unit of the School. The Director used to get Rs. 125 as additional pay for looking after this laboratory.

328. In 1947 just before the partition, the laboratory was placed under the Director of Public Health Laboratory who was appointed the Chief Analyst ex-officio. One Dr. Mohiuddin was appointed to this combined post. With the abolition of the Director of Public Health Laboratory, Government took over the Provincial Drug Control Laboratory. On 24th November 1952 Dr. P. K. Sanyal, the Government Analyst of the Provincial Drug Control Laboratory, wrote to the Director of Health Services that he could not undertake responsibility for testing drugs under the Drugs Act. The State Government were to appoint Government Analyst and for the purpose and set up laboratories. Repeated representations from the Provincial Drug Control Laboratory failed to move the Government of the day. The Director in his No. 586/53 P.D.C.L., dated 23rd November 1953, again moved the Health Service Directorate for additional staff and space but nothing was done. On 13th September 1954 under his No. 483/54 P.D.C.L. he wrote to the Deputy Director of Health Services in charge of the Public Health that he required 11,594 square ft. of space. Correspondence went on between the Drug Control Laboratory and Government on the question of space. While the laboratory authorities wanted 17 units or 11,594 square feet of space the Health Service Directorate were insisting in 13 units.

329. In 1949 Dr. P. C. Dutta, the then Deputy Director of Health Services (Medical Relief), asked Dr. Sanyal to draw up a scheme for establishment of a Drug Research Institute along with the laboratory. It

was indicated that late Dr. B. C. Roy, the Chief Minister, wanted to establish a Drug Research Institute in West Bengal on the lines of the Central Drugs Research Institute at Lucknow. He stated that there should be four different sections. A comprehensive note submitted by him is reproduced in Part II of the Report.* Nothing appears to have been done.

330. On 20th March 1957 the Government Analyst addressed another communication to the Director of Health Services, under his No. 177/57P.D.C.L., dated 18th March 1957. In this he gave details of analysis drawn in the laboratory from 1949 to 1956 which showed 300 per cent. increase in the volume of work vide statement below:

Year.	Samples analysed in Chemical Section.	Samples analysed in Bacteriology Section.	Samples analysed in Pharmacology Section.	Total.
1949	76	3	5	84
1950	97	39	9	145
1951	91	10	6	107
1952	88	39	14	141
1953	109	34	25	168
1954	120	45	21	186
1955	125	73	9	207
1956	160	66	20	246

He indicated that purchase of certain equipments was absolutely necessary:

1. Lumitron Photo-electric Fluorescence Meter Model 402 E.F. for 220 volts D.C. complete with all filters for all Vitamin estimation.
2. Zeiss Winkel Circle Polorimeter.
3. Photovolt P^H meter, operated directly from 220 volts D.C. mains.
4. Muffle Furnace (220 volts D.C.).
5. Vacuum pump (220 volts D.C.).
6. Sartorius original single pan balance.
7. Refractometer.
8. Spectrophotometer.

He insisted additional accommodation should be made available.

331. On 17th December 1957 the Director of Provincial Drug Control Laboratory wrote to the Deputy Director of Health Services (Public Health) that the Drug Control Laboratory was to be removed to a new building No. 2 Convent Lane by April 1959/60. The Government Analyst pointed out that the location of the laboratory in the premises of the School of Tropical Medicine was convenient as they could get expert advice from the various section of the Tropical School. On 1st November 1961 the Government Analyst sought permission for immediate recruitment of minimum staff for the laboratory consisting of a Pharmaceutical Chemist, a Pharmacognocist, a Biochemist, a Laboratory Technician and two Laboratory Assistants. He estimated the probable cost for the year 1961/62

*Part II of the Report has not been printed.

at about Rs. 12,000 per month. The Commission analysed 32 protocols issued under Rule 46 of the Drug Rules and thereafter made enquiries. It transpired that in a letter No. 607/62P.D.C.L., dated 12th December 1962, from the Government Analyst that the present condition of the laboratory is such that Pyrogen test should not be carried out because:

(1) There is no suitable Animal House.

(2) No arrangement for housing these animals individually in an area of uniform temperature and free from disturbances likely to excite them.

332. In the course of evidence Dr. Sanyal stated that there could be no comparison between his establishment and that at Kyd Street run by the Central Government. Dr. Sanyal was asked by the Commission to give a detailed account of costing for running a laboratory according to his idea. He was kind enough to send one which has been reproduced in Part II* of the report. Analysis of the cost is that the total recurring expense would be in the order of Rs. 4,37,000. This is considered fairly reasonable in view of the cost incurred by the Central Drug Laboratory for similar work. He also gave a list of essential equipments with details of cost, number and country of origin. The list is also reproduced in Part II of the Report with details.*

333. The Report of the Experts Committee who visited P.D.C.L. is given in Annexure to Chapter III(9).

334. The Commission did not visit the Drug Control Laboratory but was concerned to find that the statement by Dr. P. K. Sanyal and the report of the Specialists were divergent in material particulars. The Commission feels that all is not well in the Drug Control Laboratory and the matter should be enquired into by the Government.

335. The improvements of the Laboratory should follow the findings of the suggested Government Enquiry.

ANNEXURE

Report on Inspection of the Provincial Drug Control Laboratory, West Bengal

The Provincial Drug Control Laboratory, West Bengal (hereinafter mentioned as P.D.C.L.) was visited by this Committee on the 31st March 1964.

The Laboratory was established as a drug testing unit in 1938 at the School of Tropical Medicine (hereafter mentioned at S.T.M.), under the Director of S.T.M. This, it is believed, was the beginning of a drug testing laboratory in the whole of undivided India. The arrangement is reported to have functioned very satisfactorily as an intrinsic part and parcel of the S.T.M.

About three months prior to the partition of Bengal this arrangement was suddenly changed. The P.D.C.L. was shifted from under the control of Director of S.T.M. to the control of the Director of Public Health Laboratory (P.H.L.) who was also appointed as the Chief Analyst for the Government of West Bengal.

*Part II of the Report has not been printed.

This sudden and abrupt change without any prior proper arrangement for apparatus, implements and know-how stores, office, etc., completely disorganised the function of the laboratory. The respective units of Pharmacological and Chemical testing sections were housed in the respective departments of S.T.M., and the Bacteriological in P.H.L. This continued till sometime after the partition of Bengal. Later on a separate post of Government Analyst (Drugs) on contract basis was created and the administrative control of the three existing units of Pharmacology, Bacteriology and Chemistry was placed under him, although the three units continued to remain isolated and their personnel continued to work in different laboratories of S.T.M. and of P.H.L. (which is also located in the premises of S.T.M.). The Government Analyst was housed in one of the rooms of S.T.M. and his office clerk was housed either at the corner of P.H.L. or in the room of the Drug Analyst. It is interesting that though the P.D.C.L. belongs to Public Health Department, its finances are drawn from Medical Head of the Government of West Bengal.

Staff of the P.D.C.L.

Total sanctioned strength of the P.D.C.L. At present is twelve (12). This includes:

(1) Government Analyst (who is both administrative and technical head of P.D.C.L.). He is a Ph.C. from Benaras Hindu University of pre-independence days and a Doctorate in Pharmacognosy from London University.

(2) Officers in charge of Sections, numbering three (viz., Chemistry, Bacteriology and Pharmacology Sections). Excepting the present pharmacologist, the other two officers, especially the Chemist are well trained and experienced in testing of drugs.

(3) Three Laboratory Assistants (one each for the sections of Chemistry, Bacteriology and Pharmacology).

(4) Three Inferior Grade Staff (one for each of these sections, two of them attend mainly the Government Analyst's room).

(5) One Clerk for the Office (very recently a Typist has been added to the office staff).

(6) One Peon for the Government Analyst.

It may be noted here that at present the post of Laboratory Assistant in the Chemistry Section is lying vacant for quite some time.

Animal Room

There is no animal room of its own, nor does the P.D.C.L. take the help of the animal building of S.T.M. He uses animals purchased locally when required.

Animals are usually bought directly from the market. A few animals (rabbits and guineapigs) were shown to us belonging to the P.D.C.L. These were kept in wire cages in the open corridor in a crowded manner, exposed to the vagaries of nature. There is no animal caretaker to look after these few animals.

It is not surprising that with this sorry state of affairs, the P.D.C.L., particularly its Pharmacological and Bacteriological Sections, would be handicapped with regard to testing of samples, and would have to be satisfied with incomplete or inadequate manner of testing a sample given to them for test.

Some of the animals were said to have been bred in the laboratory; but no systematic or authenticated records were kept about the date of procurement and/or of breeding of any of these animals. This is an extremely unsatisfactory state of affairs which militates against all the canons of animal experimental work, far less could these be suitable for drug control work. This defect and negligence appear to be particularly significant for a drug testing laboratory. A drug testing laboratory without at least one suitable animal room under a suitable caretaker is unthinkable.

Equipment

The different sections of the P.D.C.L. mainly have to depend on the facilities and the equipments available in the departments of S.T.M. and P.H.L., and the number of their own equipments are rather few and inadequate. Even the supply of chemicals, etc., has never been regular and the different sections on some occasions have to manage testing of samples by borrowing chemicals from sister laboratories in the Medical College campus when the department of S.T.M. could not provide the same. This is particularly true of the chemistry section where comes about 90 per cent. of the total samples received for testing in P.D.C.L.

It was noted with surprise that although during the last few years a number of expensive equipments such as Spectrophotometer, Refractometer, Calorimeter, Chromatographic Chamber, Polarimeter, Ultraviolet Rays Apparatus Backman PH meter, Kymograph and several others have been purchased, (none of them has yet been utilised or handed over to the officers of the respective sections who could use them), and when day to day essential requirements could not be purchased due to, it was alleged, lack of adequate funds. Moreover, these costly electronic and sensitive apparatuses, it was noted with regret, have been still kept crowded in a small space (some of these are still unpacked); and being practically unused since their procurement the instruments are likely to have been already damaged. Some have become unworkable due to faulty storage (e.g., PH meter or due to growth of fungi on the lenses (e.g., polarimeter).

It was also noted with surprise that scanty regard was paid even in this laboratory for quality glass wares or equipments used for analytical testing.

Number and source of samples received by P.D.C.L.

It appears from records shown and the statement of the Drug Analyst that the number of samples tested in the P.D.C.L. during the last seven years varied between 90 and 130 per year. Of this 90 per cent. was attended to by the Chemistry Section, the balance was shared between the sections of Bacteriology and Pharmacology.

Sources from which the samples were received are:

(1) Assistant Director of Health Services (Drugs). This is the chief source.

(2) Assistant Director of Health Services (Equipment and Stores), West Bengal.

(3) Private sources, for which fees are charged.

It is to be considered whether this last source, through which the manufacturers of vested interest may have a free and easy access to the Drug Analyst, is desirable.

The number of samples examined by P.D.C.L. is evidently very poor, and unrepresentative of the cross-section of different types of drugs, including biologicals and others, manufactured and consumed in this State of West Bengal, A.D.H.S. (Drugs), and the A.D.H.S. (Equipment and Stores), who are mainly responsible for sending samples, should be more alive to the necessity of checking life saving and emergency drugs, such as adrenalin, pituitrin, morphine, nikathamide, septazelin, etc., and biological products, sera, antisera, antibiotics, hormones, etc. These are as much, if not sometimes more, important as chemical samples which are, of course, vastly greater in number and quantity produced in this country.

On specific query this Committee was informed by the Government Analyst that whatever samples have so far been sent to the P.D.C.L. were accepted for testing and on no account any sample was refused because of lack of facilities, both in men and material. But we were told by the Section Officers that there were many occasions when samples had to be refused because of lack of facilities and/or unavailability of proper methods of testing. It is rather disquieting that statements of important Heads of Department of the Government of West Bengal, namely, the Drug Analyst and the Drug Licensing Officer, should vary widely with regard to the type of samples which could be tested in P.D.C.L. It was, however, within the good knowledge of the Drug Analyst that for sometime past now some officers of the Central Drugs Laboratory (C.D.L.) have been appointed to act as Government Analyst for the Government of West Bengal.

Working of the Different Sections

Chemistry Section.—There is only one Chemist to test all the samples in this section. The Chemist of P.D.C.L. has been allotted about five (5) feet space on one of the working tables in the Chemistry Laboratory of S.T.M. He works there often with material help from the Professor of Chemistry, S.T.M. The Chemist does not possess any equipment of his own, nor is given the charge and responsibility about the instruments already purchased by the Drug Analyst. Some glassware supplied by the Government Analyst have often proved to be inadequate and inappropriate for analytical work.

The Chemistry Section is the most active section of P.D.C.L. examining about 90 samples yearly. The Chemist has to carry on singlehanded; even the one Laboratory Assistant allotted to him has left quite a long time ago and the post has not yet been filled up. Chemist is reported to often run short of ordinary but essential chemicals required for his routine work. He has often to beg and procure personally chemicals from different laboratories to complete his testing analyses.

Occasionally, without consulting his respective colleagues, samples are accepted by the Government Analyst, for which no suitable standard methods of analysis are available. Often in such instances even the Government Analyst fails to suggest suitable methods or technical know-how for analysing such samples. Such situations are neither congenial nor conducive to successful operation of the work or reputation of the laboratory.

Bacteriological Section.—Bacteriological section is situated in the Bacteriological Department of the Public Health Laboratory which is itself cramped for space. Only one Bacteriologist is appointed for the whole department. The number of samples examined in this section varied between 15 to 25 samples per year. The Bacteriologist has to and thus utilise all the facilities available in the Public Health Laboratory in performing his own duties.

It appears that the work in this section has lately become practically limited to sterility tests. Previously, of course, samples of antibiotics, vaccines, etc., were frequently received for tests of potency and other properties. There are, moreover, very little facilities for testing antisera and toxoids.

Pharmacology Section.—There is only one Pharmacologist employed so far. On the day of our visit he was absent. This section is located in the Pharmacology Department of S.T.M. Excepting a few small items, it possesses no equipment of its own and has, therefore, to depend on the instruments of the S.T.M. for its work. The number of samples tested in this section since 1960 varied between 9 to 17 a year. Of this, most of the samples were for pyrogen test and a couple of antibiotics for safety test and very occasionally a sample for toxicity test. It appears that samples of digitalis preparations, hormone preparations such as posterior pituitary extract, adrenalin, etc., are no longer tested in this laboratory which used to be done here before. Even in testing of the few samples mentioned above, difficulties were said to have cropped up for lack of supply of suitable animals.

The procedure followed in testing for Pyrogen calls for a few comments. The temperature of the rabbits in these tests is recorded by rectal thermometer. There is no arrangement for recording such temperatures by rectal thermocouples. As has already been noted, there is no animal room; and therefore, animals kept in the open corridor have been used for these tests openly in the laboratory in the midst of various types of activities going on in this busy laboratory.

In the recent past there has been frequent transfer and change of Sectional Officer-in-charge of Pharmacological Section. It is learnt that for about five months there was no officer available and recently a Medical Officer without any special training in pharmacological or drug control work has been placed in charge of the section. The work in P.D.C.L. particularly in the Pharmacology Section is of a very special and intricate nature demanding experience and technical skill. Therefore, before any one being posted to take charge of this section he must have a prior training in the methods of assay and testing of drugs.

General Remarks

It is a pity that P.D.C.L., which was the first of the state laboratories of its kind in India, established by the Government of West Bengal in 1938, is in such a sorry state. Instead of increasing in activity and progressing all round, it has dwindled to a mere skeleton lacking in essential facilities for testing of drugs, etc

The Government Analyst is both the administrative and the technical head of this organisation. Besides administrative work he is required to give technical help if and when required by various sections. The present incumbent is a pharmaceutical chemist, but his special field of study and work is Pharmacognosy. There may be only some remote scope for pharmacognosy in a drug control laboratory of the present type. In course of the last 14 years there has not been one single occasion when the knowledge of pharmacognosy had to be utilised. The case of sample of Tincture Zingiberis where examination and identification of crude ginger might have been called for was mentioned. But no record was produced to show that anything of the kind was done.

No instance was either cited when the Government Analyst either supplied or helped in the development of methods suitable for testing of samples by any of the three sections. It is appreciated that it is not possible for any single man to be versed with the intricate work of three different sections like chemistry, bacteriology and pharmacology, but it is desirable that a person occupying such an important position should be thoroughly versed with the intricacies of working of at least one of the constituent departments and also possess a workable knowledge of the work of other sections. Moreover, the Government Analyst should be readily available at all times during working hours for guidance of the different sections which does not appear to be the current practice.

A Drug Control Laboratory, by its very nature of work and responsibilities, should have an independent physical existence. Its portals, specially of the testing laboratories, should not be of easy access to persons not belonging to it. The very location of the laboratory in S.T.M. is liable to violate this principle. Moreover, occasions may arise when manufacturers' representatives get access into the laboratories. This should be discouraged and every step should be taken to guard against such possibility.

The system of reporting of sample tested in the P.D.C.L. calls for some remarks. The Government Analyst is the authority entitled to sign the Report on behalf of P.D.C.L. It is, however, desirable that the report should also bear the signatures of the section officers against relevant portions of the report. The interpretation of findings of the various sections on a single sample requires careful deliberation, in absence of which there is risk of misinterpretation. The case in point is illustrated hereunder.

Excerpts from a report on the analysis of Atropine sulphate (inj.) by the P.D.C.L.

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5. Name of drug purporting to be contained in the sample injection Atropine sulphate 1/100 gr. in 1 c.c. ampoules. No batch number given, Bengal Research Institute—

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6. Condition of seals on the package Seals intact.

7. Result of test or analysis with protocols of test applied detailed/ below.

In the opinion of the undersigned the sample referred to above..... .....

is of standard quality

as defined in the Drugs Act, 1940, and rules thereunder for the reasons given below:

The sample contains Atropine like substance as shown by the pharmacological tests—

Report on the analysis of Atropine sulph. (inj). Character—clear colourless liquid.

Test for Identification—A small quantity of the sample was taken and made alkaline with ammonia and extracted with chloroform.

1. A portion of the residue was acidified with HCl and gold chloride solution added a yellowish ppt.

2. To another portion of the residue 5 drops of HNO_3 added and evaporated to dryness on water bath and when alcoholic potassium hydroxide added—a faint violet colouration, not very distinct.

Date.....

Government Analyst.

3. The sample responds for the test of sulphates—

The sample is insufficient for other tests. Though the sample gives indications for the presence of an alkaloid but the identification test for atropine is not very distinct.

2. Biological Assay:

The sample has been tested biologically and has been found to elicit fully the specific effect of Atropine.

(Sd.) P. K. Sanyal,
Government Analyst.

It has been felt that prior consultation with the section officers might have avoided these difficulties. It may also be pointed out here that in this case the sample concerned was an injectule of Atropine sulphate. It is strange that it was not considered necessary to test the sample for sterility and it is surprising that on the face of such incomplete examination, the injectule was certified by the Government Analyst as of standard quality.

The purchase of expensive and sensitive precision instruments and appliances without any clear cut plan as to when they are going to be utilised, their storage, etc., should be discontinued. It has been brought to the notice of this Committee that Reports of this Laboratory have been utilised by manufacturers for advertisement purpose. A case in point is the report on (Kontracep), manufactured in India by Respo Laboratories—which published the report signed by Government Analyst for advertisement. The practice merits strong disapproval. (Appendix IV).*

The appointment of officers of C.D.L. to act as Government Analyst for the Government of West Bengal itself points to some existing defects in the P.D.C.L. which merits a thorough enquiry.

The Expert Committee, therefore, likes to make a few recommendations as stated below. The P.D.C.L. must be reorganised forthwith. It does not speak well for the Government of West Bengal to ask Drug Manufacturers to set up expensive and extensive paraphernalia while its own drug testing laboratory is in such a poor state.

1. The Drug Testing Laboratory (P.D.C.L.) must be located in its own house. It is learnt that the construction of Public Health Laboratory of the Government of West Bengal has been completed and is lying ready to be occupied. The P.D.C.L. may be shifted to this premises, provided—

(a) it is allotted adequate and exclusive accommodation, and

(b) it is completely separate from the rest of the laboratories, having its own separate entrance.

*Appendix IV has not been printed.

2. The P.D.C.L. should have an independent administration under the charge of a Director, who should also be the Chief Government Analyst (Drugs) to the Government of West Bengal. He should preferably be a medical scientist with adequate experience of drug testing and allied work.

3. Each of the Sections should be headed by a Sectional Officer-in-charge, who should also be designated as Government Analyst.

4. Reports of testing from each Section should be signed by the officer-in-charge. The integrated report from different sections on a single sample should, in addition, be countersigned by the Chief Analyst after discussion with respective sectional officers, if needs be.

5. Each Section should have one Senior Officer and more than one Junior Officer—the latter working as understudy. This will obviate the posting of persons, without any knowledge of drug testing work, in charge of a Section when occasion arises, as has been the case so far.

6. The post of the Director of P.D.C.L. and of the Sectional Officers and their understudies should be considered as specialist posts, and emoluments attached to them should be commensurate with the responsibility of these jobs. The practice of frequent transfer of these officers should be discouraged.

7. The P.D.C.L. laboratories should be regarded as protected areas and access for outsiders to these laboratories should not be allowed.

8. The P.D.C.L. must have its own properly equipped, modern Animal House under the charge of a qualified caretaker. Animal should be bred in this animal house and testing work should be carried out with such in-bred animals. In addition to this animal house there should be arrangement in the pharmacological and bacteriological laboratories for keeping animals in separate rooms.

9. The A.D.H.S. (Drugs) should make it a point to seize samples of drugs at random from the pharmaceutical concerns, wholesale dealers and also from sale counters. They should not only seize drugs of indigenous manufacture, but also drugs of foreign origin. A.D.H.S. (Equipment and Stores) also should adopt the practice of sending certain percentage of samples from every bulk purchase and also send samples at random from different hospitals and dispensaries.

10. The Drug Control Laboratories, besides carrying out routine testing work, should also undertake research work with a view to find out suitable and/or better methods of drug testing; and also with a view to review the analytical methods in the Indian Pharmacopoeia.

11. It transpired during our visit to the P.D.C.L. that there is no arrangement for the maintenance of the various "International Standards" for drugs in this institution. This practice is most unsatisfactory and steps should be taken to rectify it with immediate effect.

12. The P.D.C.L. should also undertake to train personnel in its different disciplines with a view to make available properly trained men to the drug industry until the proposed State Drug Research Laboratory is established.

13. It was also noticed that there was no Statistician attached to any of the sections of the Drug Control Laboratory. As the work undertaken in these laboratories involves quite a lot of statistical evaluation of results, it is felt to be essential that at least one properly qualified Statistician be added to the staff of the P.D.C.L.

14. It is envisaged that occasions may arise when the services of Pharmacognosist may be required; particularly if in future it is decided to undertake testing of crude materials (specially plants) used by the manufacturing concerns. Therefore, a properly trained Pharmacognosist (in the rank of Junior Section Officer) should be attached to the Chemistry or the Pharmacology section.

15. Besides the properly staffed office for the P.D.C.L. each of the section should be provided with one Clerk-cum-Typist.

16. There should be a library of its own.

17. There should be scope for future expansion.

4.1. MALPRACTICE (GENERAL REMARKS)

(1) MALPRACTICE (GENERAL REMARKS)

336. "Malpractice" in drugs has not been unknown even in ages past. It covers a wide range of irregularities. Analysis of evidence given by the members of the medical profession has failed to indicate with any degree of certainty the extent of adulteration of drugs. Some medical practitioners, unfortunately, were not even aware of the provisions of the Drugs Act. Others were reluctant to report to the State Drug Controller presumably because they did not consider it worthwhile to follow up, on the ground that nothing would be done.

337. Adulterated drugs can be categorised spurious and/or sub-standard, whereas the term "misbranded drug" as used and defined in the Drugs Act is a composite one. The Commission has discussed and recorded its views on nomenclature elsewhere in this Report. Spurious drugs, for the purpose of this report, are those which are deliberately adulterated. Some are entirely spurious, that is, they do not contain any of the ingredients declared in the brand; some are partly spurious in the sense that they do not contain the declared quantity and the specified quality of the ingredients. Sub-standard drugs can be subdivided as follows:

(1) Drugs which have deteriorated because of indifferent storage, or where the shelf-life of drug has expired;

(2) Drugs which are not up to the specified standard because of ineffective statistical quality control at the various stages of manufacture because of—

(a) Lack of laboratory facilities,

(b) Lack of technical knowledge,

(c) Basic defects in the raw materials.

338. It was clearly impossible for the Commission to apprehend or find out who are responsible for adulterated and spurious drugs. The persons responsible for manufacture of these drugs are no doubt experienced criminals. They do not possess any Drug Licence nor are the location of their premises known to the authorities. The Commission had to maintain a secret cell for investigation, which was thought necessary by the Members of the Commission at their fourth sitting. This cell, headed by the Member-Secretary of the Commission, consisted of the Assistant Secretary and some special informers. Surprise visits were made and sources were engaged to locate these factories. One was found to operate in the early hours of the morning, namely, between 3 a.m. and 7 a.m. The Commission found that there are a number of dealers in Canning Street, Bagri Market and Barrabazar area where well-known products like Chloramphenicol are sold at such low prices as would clearly prove that they could not be up to the standard. There are shops which sell drugs like Calcium Gluconate, Antibiotics and Sulpha drugs in polythene bags. It is really a matter of genuine surprise to the Commission that this sort of things have been allowed to continue. A medical practitioner of Howrah stated that the manufacture of these spurious drugs are sponsored by a group of persons consisting of three leading medical practitioners, one financier and one biochemist of repute. He maintained that they manufacture spurious drugs which do not contain any quantity of the medicine of the brand. They are sold to the dealers at the Bagri market. The dealers sell them to retail chemists. They in their turn sell 20 spurious for every 80 genuine ones. Duplicate batch numbers are printed on the spurious drugs and

care is taken to see that the buyers do not get genuine and spurious drugs bearing the same batch number.

339. This appeared to be a plausible statement and the matter was investigated into very carefully. It transpired that what the witness had said was to some extent true. In view of this the Commission would recommend to Government that further investigations in these matters be carried out by senior police officers.

340. The Commission has on record a statement by a leading pharmaceutical firm of Calcutta that it had been brought to their notice that one of their ex-employees, in collaboration with outsiders, was manufacturing sub-standard and spurious drugs simulating their own products and were also printing their labels. This was said to have been brought to the notice of the Assistant Commissioner of Police, who pursued the investigation with vigour. The premises were searched and the case was sent up for trial. But the Commission came to learn that the case had ended in acquittal.

341. The reasons for adulteration of drugs are many and varied. It is principally a human failing and is an indication of the general malaise in the urban society of India. Today there is adulteration in practically everything, food, clothing, building materials, cosmetics, and even drugs. There are no standard of values and the main interest is to make more money without paying taxes.

342. The Commission, however, distinguish between adulterated drugs and sub-standard drugs, the latter of which may be the result of indifferent storage and other factors like the want of expert supervision. Some drugs are not up to specification, not because of any deliberate attempt on the part of the manufacturer but because the system and standard of assay and measurement are defective and statistical quality control is wanting. Therefore, the public may have reasons to think that there is a certain amount of deliberate adulteration.

343. The Commission examined the Annual Report of the Central Drug Control Laboratory and collected the following informations:—

	Examined	Sub-standard.
Imported drugs—		
1955-56	868	94 (11%)
1957-58	519	33 (6·3%)
Patent and proprietary medicines—		
1955-56	301	24 (7·4%)
1957-58	132	17 (11·4%)
B. P, B. P. C. and others—		
1955-56	362	24 (6·8%)
1957-58	519	33 (6·3%)

344. The figures disclosed that even among the imported drugs there is a certain quantity which is sub-standard, but there appears to have been a perceptible decrease in the latter years. With patent and proprietary medicines, the percentage has gone up from 7 to 11 in three years, while the percentage of sub-standard B.P., B.P.C., and other drugs is steady around 6 per cent.

345. A compulsory system of packaging all tablets in aluminium foils, although it may not prevent adulteration, is likely to prevent their rapid deterioration into substandard quality.

346. During the course of its sittings, the Commission came across widely varying ideas among medical men on the problem of adulterated and sub-standard drugs. An eminent consultant in his evidence said that it is the duty of the attending medical practitioner to ensure that the drug that he prescribes is correctly served and at a fair price. Another consultant in the same speciality of medicine said that his duty ended with prescribing the best medicine for the ailment of his patient. The supply of genuine and potent medicines and at a fair price, according to him, is the responsibility of some one other than the doctor. A third consultant said that to avoid risks of sub-standard or adulterated drugs he prefers to prescribe for his patients only drugs made by overseas manufacturers of established repute even if these drugs cost more than the doubtful indigenous drugs.

347. The Commission would emphasise the great need for manufacture in India of genuine and dependable drugs of correct potency and purity, and the sale of this life-saving commodity, at a fair price. This can be possible only if the medical men are alert to the problem on the one hand, and on the other, the manufacturers are conscious and proud of their products which play a vital role in the health and life of the nation.

348. Another reason for retail of adulterated sub-standard drugs is that while some of the pharmacists always get their stocks from reputed firms only, others get their supplies through agents of less repute who offer attractive rebate. It is, therefore, desirable that the pharmacists should, as far as possible, purchase their stock directly from importers or authorised and well-established stockists. It will be desirable for the pharmacists to maintain a record of their sale to customers and purchases from manufacturers. In case there is any doubt about the quality of the drugs, they could be traced back to the manufacturers. At the same time the Commission feels that the public should also be educated. Recently in the United States there has been awareness in Government circle that by mere policing, drug control cannot be enforced and that for the proper operation of the Food and Drugs Act education of the public is very necessary. In that country, the Special Citizens' Advisory Committee commended an orientation of Food and Drug Administration with emphasis on education of consumers and producers and co-operation with the industry. The Advisory Committee suggested formation of an institute which will consist of the existing bureaus of Pharmacology, Nutrition and Food and Drug Standards.

349. The Commission would recommend that a similar approach to the subject be made in West Bengal. Our newspapers in the past hardly ever reported on anything about drugs. Advertisements which appear in the Indian almanacs and on the wall-posters are mostly misleading. The drugs are either spurious or of doubtful therapeutic value. The Commission would, therefore, recommend that Government should have a standing machinery for publicity to educate the public regarding the proper use of drugs, what should be done in case the drug is suspected to be spurious, and also educate the public on the dangers of using unproved drugs prescribed by quacks.

350. A form of malpractice also exists in the sale of certain Homeopathic and Ayurvedic medicines and of Homeopathic injections. The intelligence wing of the Commission located a company and brought the matter

to the notice of the drug control authorities, as they felt there was considerable risk in what this particular firm was doing, namely, selling "homeopathic injections." The practice of Homeopathy by persons not fully qualified is another form of malpractice and insistence on proper medical qualifications for the practice of Homeopathy is recommended.

351. Another form is the sale of formulations containing ingredients of the British Pharmacopoeia under Unani or Ayurvedic names. A few manufacturers in the city have built up an extensive and lucrative business. Neon lights, bold advertisements in hoarding sites, publicity in and around labour colonies, are openly resorted to by them. The Commission was also informed about the method of preparation of their formulations. They had imported foreign machineries like Sieving Machine, Triple Roller Mill, Vacuum Distilling unit, Filters (Horizontal Plate), Oil Press made in West Germany, Soxhlet Extractor, Autoclave, Ball Grinder, Colloid Mill, Granulator, Rotary Tablet Machine, Pill Making Machine, Tablet Wrapping Machine, Vacuum Evaporator, Vacuum Liquid Filling Machine, Sealing Machine, Labelling Machine, Bottle Washing Machine. But requests for similar plants and equipments from several other reputed concerns of long standing and engaged in pharmaceutical drug manufacturing were not entertained. The Commission was informed that the concern referred to above, engaged in the manufacture of Ayurvedic medicines under the garb of western medicines, imported these machineries during the last three years. The Government of India in the Ministry of International Trade in their letter No. 7/23/63-I.M.P., dated 2nd August 1963, informed the Commission that no application for licence for the import of machinery appeared to have been received by them between 1959-63. This appeared to the Commission rather peculiar and further investigation should be made by the Ministry concerned.

352. This firm, like others, makes Emulsions, Tinctures, Ointments, with B.P. ingredients and as already pointed out, sells them under Sanskritised names. Some of them have large alcohol content up to as much as 81 per cent. v/v. Similarly, other drugs contain Codeine B.P., Tr. Ipecac B.P. This is a form of malpractice which should be put down with a heavy hand. This firm has been given import licence for Peppermint Oil, Menthol, etc. Some of the items are valued very high. For instance, during 1961 they imported 1,413 lbs. of Phenacetin from Monsanto Chemicals Ltd., London, at Rs. 6,600. During 1961-62 they imported Rs. 28,354 worth of Pepperment Oil B.P. (1958) from Holland. They imported Clove Oil B.P. (1958) worth Rs. 6,646 weighing 646.14 lb. from H. E. Daniel & Co. There is a heavy blackmarket in Oil of Cloves. From the list of medicines supplied by them it was not clear if their entire stock of Oil of Cloves had been used in the manufacture of the medicaments. The Commission would recommend an enquiry into the affairs of such concerns. The Commission learnt that United Pharmaceutical Manufacturers' Association had reported to the Central Health Minister regarding manufacture of spurious "Water for Injection" in West Bengal, which had been referred to in her letter to the Chief Minister, West Bengal, as well as in a statement to the Parliament. On the Commission's attempt to meet the Associations' office bearers, the Commission found that the Association was not in existence.

353. Nevertheless, it is a fact that following the discovery of Penicilin and its manufacture by Government of India at Pimpri, the demands for Water for Injection rose sharply. A number of ill-equipped concerns commenced manufacture of Water for Injection completely in disregard of the standards specified at page 64 of the Pharmacopoeia of India, 1955, first edition.

354. Another form of unethical practice is surreptitious sale of physicians' sample even though the drug is genuine.

355. It has been represented to the Commission confidentially and the Commission has reasons to believe that the representation is not very much exaggerated, that some of the concerns manufacturing medicine in India send large quantities of samples to physicians. An unscrupulous medical practitioner may prescribe particular brands of drugs and ask the compounder to serve the medicine. The compounder at times could empty the contents of one of these sample phials into a paper envelope and sell it to the patient.

356. In recent years the public have become conscious of the importance of drugs. Over-emphasised publicity given to certain categories of new drugs goes to convince the public that drug is important as the doctor. This altered importance had certain repercussions, one of them being self-medication. The patients study the medical literature enclosed in the cartons and administer the drugs to themselves. This self-medication or self-doctoring of potent or even poisonous drugs is fraught with considerable danger to human life and health. Self-administration has also an unfortunate repercussion—drug addiction.

357. The rate at which drug addiction is increasing makes the Commission sound a note of caution to the health authorities that vigorous check should be kept on the sale and distribution of the following classes of medicine:

(1) Sedatives—like barbiturates;

(2) Stimulants—like cocaine, benzidrine;

(3) Tranquilisers;

otherwise malpractice will increase.

358. Another group of drugs which are used in self-medication and are habit forming is Aphrodisiac. These are available from indigenous sources and also are imported from foreign countries. Prices vary to suit all pockets.

359. It was also brought to the notice of the Commission that there is considerable cocaine addiction in Calcutta and the adjoining industrial areas.

360. The only way to prevent sale to addicts, who patronise the black-market, is educating the public and strict control on sale of these drugs.

4.2. MALPRACTICE IN DISTRIBUTION

361. Distribution in the U.K. is controlled by the proprietary Articles Trade Association. All supplies are through the wholesalers, who get a discount of 12½ per cent. on the ex-factory price and allow 33 per cent. discount to the retailers on listed price. The Association ensures fair price in their distribution system and prevents any spurious or sub-standard drugs from coming to the market. In the U.S.A. the drugs reach the patients through wholesale druggists, manufacturers representatives or by direct supply, physicians supply house and hospital pharmacies. The wholesalers are subdivided into:

1. Full wholesaler.
2. Specialist service wholesalers.
3. Full line mutual wholesalers.
4. Special service distributors.

362. Fair Trade Regulations control discount, which is generally 40 per cent. for retail pharmacies, and 16 to 17 per cent. for wholesalers. This does not mean that there are no malpractices in either of these two countries. Dr. Louis Lasanga, Head of the Clinical Pharmacy Division of Johns Hopkin, in his testimony before the Kefauver Committee stated "The problem of built in obsolenscences is tied is not only to the appearance of new and better substitutes but to the miserable quality of drugs that are issued each year. The advertising agencies are being asked to sell to the medical profession a whole bushel basketful of sows ears for silk purses every year. This plethora of poor compounds, and of new mixture of old agents that appear each year confuses physicians. It raises the cost of drugs, I think and may harm patients either through keeping them from adequate therapy or by causing serious side effects." (Hearing Part 14, page 8140.) The role of sales promotion in the distribution system has been adversely commented upon by other specialists also. Dr. H. J. Weinstein, a former director of a Division of Pfizer, stated before the same committee: "The entire promotion and advertising programme has been directed at the physician in recognition of his special role. He has been taught one might almost say brainwashed, to think of the trade name of the drug at all times. Even new disease states have been invented to encourage the use of some drugs. He has been exposed to remarkable little information regarding the drug he is asked to prescribe. He is given practically no information as to the cost of the drugs to his patients. Instead he is seduced with grimmicks of all sorts in an attempt to make him loyal to a particular company or a particular drug ....." (Hearings Part 18, page 10246.) The practice of developing slight molecular modification with very little or no special therapeutical value is equally reprehensible. Erythromycin is a case in example. This was discovered in the works of Messrs. Eli Lilly & Co. and claimed to be effective against staphylococci and other cocci. This was in 1952. In 1953, Messrs. Charles Pfizer introduced an analogue, Carbomycin, which was advertised as, as effective as Erythromycin. It was withdrawn as it was developed in Europe and tests by Dr. Dowbing and his colleagues revealed that it did not possess any added advantage and its introduction in U.S.A. was stopped. But, Messrs. Charles Pfizer & Co. introduced another analogue of Erythromycin, Oleandomycin, and followed it up with Triacetyloleadomycin claiming higher blood concentration by oral administration. Lilly hit back with propyonyl salt of Erythromycin with identical claim, of higher blood concentration.

363. Combination of drug stores and medical practice which is very common in West Bengal is a source of malpractice. In Germany permission is given only in those localities where there are no dispensing chemists. In France also a medical practitioner can have a pharmacy on the recommendation of the Regional Director of Health only if there are no pharmacies. They can keep medicines which have been approved by the highest professional bodies of Physicians and Pharmacists. Medicines can be sold to the public at prices fixed by the Ministry of Public Health and Population, on the recommendation of the Federation of Syndicate of Pharmacists.

364. The distribution system in West Bengal is complicated. Drugs produced in West Bengal, that is mostly in and around Calcutta, are sold to the retailers:

(a) By direct despatch from the factories.

(b) Through Journeymen or Retailmen or canvassers.

(c) By wholesalers.

(d) By stockists.

365. Discounts vary from product to product which is understandable but it also varies from season to season which is incomprehensible. The journeymen or canvassers attached to smaller units are the only media for advertisement of the products, mostly formulations. These drugs sometimes fail to prove satisfactory. The so called medical literature accompanying these formulations are written by the manufacturers themselves and as such may not be scientifically correct. These fortify the journeymen or canvassers, some of whom may be medical men themselves, in convincing the pharmacy-owning and other doctors, about the efficacy of the products. Sometimes, they leave stocks of these proprietary drugs with the retailers without payment. This procedure is another form of sales promotion of the drugs.

366. Drugs manufactured outside the State, and mostly in Maharashtra and Gujarat either by Indian firms, or by Collaboration Units, or by foreign companies are distributed by stockists. These stockists generally sell to retailers at varying prices. In the distribution trade, they could and sometimes do create artificial shortages leading to black-market. The mixed antibiotics sold by these firms require careful inspection, both with regard to their efficacy and storage.

367. It is therefore desirable that the manufacturers should supply direct to retailers, who in turn should be qualified and registered pharmacists. The practice of selling some drugs by pan-biriwalla grocers and general merchants should be stopped. Rule 62A of the Drug Rules, added under Government Notification No. F. 10-21/49, dated 10th March 1963, authorising the issue of licence to itinerant vendors should be modified and issued only in very exceptional cases. Proviso to Clause C of the said rule exempts the travelling agents of licensed manufacturers from taking out licence in Form 21-A.

368. Rigorous enforcement of the provisions of Drugs Act and Rules is essential. It should also be the responsibility of the manufacturers to ensure that only the honest and dependable stockists are entrusted with the work of distribution. The premises must be easy of access and situated in hygienic surrounding. One has only to walk through Canning Street or peep into the Mehta Buildings and Bagree Market to be convinced of the necessity for shifting the venue of wholesale trade of these imported products.

369. Regarding the question of rebate and Commission, it is difficult to make any definite recommendations as the price of drugs is subject to sudden change and the risk of obsolescence of the drugs is always there.

370. The purchase policy of some Governments may indirectly encourage manufacture of sub-standard drugs. For example, Mr. A. A. Smith, Managing Director of Upjohn Ltd., in an address to the Marketing Society in the U.K. criticised the action of the British Health Ministry in purchasing drugs from other countries of standards not quite up to that in the British Pharmacopoeia. Pressure was being brought to bear on National Health Service doctors to prescribe these, which were according to them sub-standard.

371. To sum up, malpractice in actual distribution system and allied sales promotion is wide-spread and inherent in the existing conditions in West Bengal. Without disrupting the current system much can be achieved by voluntary control by manufacturers and retailers. The State Government can assist by the following:

(a) By ensuring that journeymen and canvassers, medical and non-medical, are licensed. They should be legally liable for vending spurious and sub-standard drugs.

(b) By insisting on the manufacturers taking back time-expired drugs. The date of manufacture and the date of expiry wherever applicable should be specified on the label. The statutory provisions regarding labelling detailed in Rules 94 to 106 of the Drug Rules (1945) should be strictly enforced by Government.

(c) By following a rational policy in procuring annual stocks of drug for hospitals, etc., without compromising quality for price and by purchasing from established manufacturers, avoiding unproved formulations, fancy antibiotics and synthetic products.

4.3. MALPRACTICE IN MANUFACTURE

372. In the drug manufacturing trade there are well-established codes of conduct in some of the Western countries. These are voluntarily enforced on themselves by corporate bodies. Statutory regulations no doubt exist, but the control is essentially voluntary in character, and the aim is to supply drugs which strictly conform to the standards prescribed in the official pharmacopoeias or codes.

373. Government of India constituted a permanent Indian Pharmacopoeia Committee in 1948, under Notificaion No. F.-1/48-D.S., dated 23rd November 1948. The first edition of the Pharmacopoeia was published in 1955. During the interim period, the manufacturers were asked to follow the British Pharmacopoeia, or the British Pharmaceutical Codex, or any other prescribed pharmacopoeia or "adopt the Biological Standards of the World Health Organisation", vide entry 4 in Schedule to the Drugs Act (1940). The eighth British Pharmacopoeia was published in 1953. In 1958 another edition was published. Certain monographs have been added as on Butabarbitone, Chlorotetracycline, Erythromycin, Folic Acid Tablets, Tetracyclines, Piperazine, and a number of monographs have been deleted as on Calcium Chloride, Clove Inj. Morphine and Atropine, Inj. Gonadotropine, etc., but none of these changes have yet been incorporated in the Indian Pharmacopoeia.

374. It is further understood that another edition of the British Pharmacopoeia came out in 1963. As the Indian Pharmacopoeia is not up to date, the manufacturers are in a mess. Some of them purchase low-priced Russian Pharmacopoeia which is available in English in Calcutta. The U.S. Pharmacopoeia (XVI) is not available anywhere in West Bengal except with the United States Information Service, which they very kindly lent to the Commission for its use.

375. It came to the notice of the Commission that most of the small-scale manufacturers did not take full precautions needed for making drugs. Much of this is the result of ignorance rather than any mala fide intention. In the absence of mens rea, it would be unfair to call this malpractice.

376. The intelligence cell of the Commission paid a surprise visit to an establishment preparing Water for Injection. A science graduate was in charge. He was ampoulising, under most insanitary condition, double distilled water. The fault is essentially that of the State Drug Control organisation in having issued licence to the firm. The proprietor-chemist in his evidence before the Commission admitted that he did not know how to test for Pyrogen or sterility of water. Ever since the present Commission was set up, the Inspectors appear to be over-active and insist on air-conditioned rooms even for small units making ordinary formulations.

377. All drugs for injection should pass the sterility test. Unfortunately, very few of the manufacturers of injections (who hold special licence in Form 28-A for manufacture of drugs specified in Schedule C to the Drugs Rules) observe these rigorously.

378. Biological tests and assays are of vital importance in the drug industry. Both cylinderplate assay and turbidimetric assay call for control study of a high degree of precision. Calculation for assay preparation involves plotting of standard curves from corrected averages. In bio-assay, the controlling factor is variability of the indicator. The equipment and personnel for these controls and assays were found inadequate in many cases.

379. The licensing authority should take special precaution in licensing manufacture of Schedule C and C(1) drugs, as well as for water for injection, with particular reference to sterility, pyrogen test and bio-assay.

380. Suggestions for preventing other forms of malpractice in manufacturing have been given under Quality Control (Ch. II: 5) and Testing (Ch. II: 7).

381. To sum up, the Commission did not come across adequate proof to justify the belief that all drug manufacturers in West Bengal deliberately produce sub-standard or spurious or adulterated drugs. Considerable agitation followed statements in Parliament, referred to in Chapter I (Page 2); As noted in Ch. IV (Page 224) the United Pharmaceutical Manufacturers' Association, who were reported to have written to the Central Health Ministry, could not be traced nor did any one come forward to give evidence before the Commission in spite of wide publicity given in the leading daily newspapers of the city.

4.4. MALPRACTICE IN SALE

382. The Commission has reasons to believe that malpractice in the sale of drugs is not inconsiderable.

383. Malpractice regarding quality has been dealt with under Quality Control, i.e., Testing of Drugs, and under Storage and Distribution.

384. Regarding price, there appears to be a periodic racket in imported drugs sold by local vendors whenever there is a shortage of drugs artificially or otherwise created.

385. The Pharmaceutical Enquiry Committee (1954) at page 161 of their Report have detailed the operation of spurious drug manufacturers and their method of sale through canvassers.

386. Strict police control through the State Drug Control (Price) Act of 1950 may perhaps, be the only solution.

4.5. STORAGE OF RAW MATERIALS

387. This subject does not appear to have received serious consideration by the drug and pharmaceutical manufacturers in India, except by a few concerns.

388. Solid materials are stored either in bulk in the open or in bottles and containers inside a store-house. The solids generally stored outside are ores, sulphur, roots, plants, herbs, which do not deteriorate or undergo change in quality if left in the open. In the matter of storage of these elements, special care appears to be needed for these articles which have elements of poison in them as they are liable to be stolen and misused for criminal purposes. Indoor storing of the drugs and barrels is generally quite satisfactory because these materials are imported and are high priced. For solid materials stored in containers like barrels and drums, due care should be taken to prevent deterioration from contamination with the metallic or cellulose surface.

389. Liquid materials also require very careful handling and storage. Special care is needed for acids and alkalis. Most of the smaller drug manufacturers do not appear to have any idea regarding the quality of glass. Storing acids and alkalis in the proper type of glass containers is very essential.

390. Very few of the small factories store gas. The larger ones store them under fairly satisfactory conditions.

391. Storage in factories is essentially a matter of routine, except for poisons and delicate chemicals. No specific suggestions can be given. Inspectors should exercise strict vigilance during their visits.

Malpractice in Storage

392. The Drugs Act and Rules (1945) stipulate storage of biological products like vaccines, sera, and heat sensitive drugs in cold storage. Inspection of the premises of manufacturers disclosed that in quite a number of them the cold storage plant was either out of order, or working indifferently. They complained about non availability of Freon and Arcton gas for which the blackmarket price in Calcutta is said to be Rs. 32.00 per lb., against the normal price of Rs. 8.00 per lb. Two leading concerns dealing in them reported that no stock was available. The Commission would invite the attention of the State Government to this state of affairs, where bona fide manufacturers cannot keep their delicate products under proper storage conditions because of non-availability of gas. They would recommend that the State Government should hold stocks of gas, as they do of some other essential materials like lead, zinc, etc., and sell the gas to the drug manufacturers against requisition to be countersigned by the Drugs Control Authority.

393. Weather conditions in India are so variable that transit of delicate drugs like Vitamine is risky. Railway authorities should provide cold storage transit facilities.

394. The storage conditions with the stockists and wholesalers with a few notable exceptions are unsatisfactory. The Drug Control Administration is as much responsible for the state of affairs as the stockists. The licences of the offending stockists should be cancelled and the stock subject to detailed assay for potency and effectiveness. If found unsatisfactory the stocks should be confiscated and regenerated or destroyed as may be necessary.

395. The Commission found that in the case of many of the retailers also, there is considerable room for improving the storage condition of drugs. The Commission strongly feels that regular inspection of the premises is essential so as to enforce strict compliance with the requirements of the rules.

4.6. MALPRACTICE—PROTECTIVE PACKING

Protective Packing

396. Some of the malpractices, including sale of spurious tablets in old containers, sale of physicians' samples or time-expired tablets can be stopped by compulsory strip packaging.

397. The properties of heat-sealable aluminium foil are suitable for strip packaging. The advantages of aluminium foil are:

(1) *Impermeability.*—Foil of the correct gauge is impermeable to moisture and gases.

(2) *Non-toxic.*—Foil is inert, microorganisms cannot thrive on its surface. The heat sealing medium contains no toxic substances.

(3) *Light and Heat Barrier.*—Foil reflects 96 per cent. of radiant heat and is a complete barrier to light. Deterioration by heat is minimized and colour change by the action of light is prevented.

(4) *Utility.*—The daily or weekly dosage of tablets can be conveniently carried in the handbag or packet and will not be contaminated by dust or pick up odours from tobacco or cosmetics.

398. Aluminium foil can be classified into three main groups—

(a) Foil coated with thermo-plastic synthetic resinous compounds.

(b) Foil coated with or laminated to thermo-plastic film (Polyethylene).

(c) Foil laminated to a plastic film and coated on the reverse side with a thermo-plastic synthetic resinous compound.

399. All these can be printed with trade marks formula, batch number and date of expiry. Tablets which are sensitive to moisture or highly hygroscopic can be duly protected. Tablets with very short shelf-life can be packed in foils with lower coating weights.

400. The foil can be subjected to vacuum test. Shelf-life is tested by water vapour penetration rate. Strips are selected by random sampling. They are placed in a cabinet at a steady temperature of 38° Centigrade with 90 per cent. relative humidity.

401. They are checked at 24-hour intervals. Details of water-vapour permeability of packing materials are given in Packaging Review Data Book 1961 and Modern Packaging 1958, 1959.

402. Specifications of the tamperproof packing for all categories were furnished by a leading Calcutta firm.

These are summarised below:

Tablets.	Powders.	Solutions.	Emulsions	Vaccines	Ointments.
Roll Seal Pilferproof closures for bottles.	Roll seal Pilferproof closures for bottles.	Roll Seal Pilferproof closures for bottles.	Roll Seal Pilferproof closures for bottles.	Vials with Pilferproof tear-off seals.	Collapsible tubes.
Aluminium foil capsules for bottles.	Aluminium foil capsules for bottles.	Aluminium foil capsuls for bottles.	Aluminium foil capsules for bottles.		
Strip packs of laminated materials.	Strip packs of laminated materials.				
Sealed tinplate cans.	Sealed tinplate cans.				
Rigid aluminium tubes with pilferproof overseals.					

403. The following machineries are required for tamperproof packing. The sources are also indicated below:

1. *Roll-Seal pilferproof Closures.*—Sealing equipments are manufactured in India.
2. *Aluminium Capsules.*—The equipment for sealing these capsules into bottled products is imported.
3. *Laminated Strip Packs.*—Heat-sealing machines for strip packs are currently being manufactured in India. Machines are also imported by packers from Germany and the United Kingdom.
4. *Sealed Tinplate cans.*—Hand-operated and automatic can closing equipments are manufactured in India.
5. *Tear-off Sealed.*—Equipments for high speed application of tear-off seals is imported.
6. *Tube-closing equipment.*—Available locally.

404. *Raw materials required.*—Raw materials required are indigenous. Details are given below—

(a) Roll-Seal pilferproof closures—Aluminium sheet.

(b) Foil Capsules—aluminium foil.

(c) Laminated Strip Packs—laminated combinations of aluminium foil, polyethylene and paper.

(d) Cans—tinplate.

(e) Tear-off seals—coiled aluminium strips.

(f) Collapsible tubes—aluminium slugs.

405. The packaging cost element of drug as percentage of retail prices varies considerably, depending of course on whether the drug is a low cost analgesic tablet or a costly antibiotics. However, major pharmaceutical manufacturers estimate their packing costs at 5 per cent. of the retail prices of drugs. In the matter of costing of dry packaging one has to take into account the question of adequate protection against atmospheric conditions, chemical reactions, bacterial contamination, the hazards of transportation over long distances, poor handling methods, adverse storage conditions and the everpresent danger of substitution and adulteration. Additional considerations of economy which guide the choice of a package are freight, storage space and shelf life.

406. The standards of packaging for drugs should be specified immediately. The cost involved would not be incommensurate with the benefits to be derived. Almost all the machinery and raw materials required are available in India. Although the cost of manufacture of aluminium foils coated with synthetic material is fairly high, Government should insist on tablets being packed in them. Tamperproof foil suitably stamped would definitely prevent adulteration.

407. Strip packing materials in use were examined by the Commission. Aluminium foils and paper treated with Polyethylene are used. Some of the firms print the name of the drug with firm's name of the foil while others keep it blank. The strip is pinned inside thick paper-cover on which is invariably printed the details required by the Drugs Act.

408. The Commission found that some drugs did not exhibit the details on the pilferproof strips. It then becomes easy to get hold of the printed outer paper cover and substitute the strips with substandard or adulterated tablets. Some multi-vitamin tablets manufactured in India are packed in strips. The individual tablets are not separated by perforations. The

result is that when one tablet removed by tearing, the tear is irregular and comes fairly close to the next tablet leading to deterioration of the drug. The Commission would recommend that there should be statutory compulsion on perforation of strips separating individual tablets. Some of the tablets sealed in transparent paper capsules were found to have undergone changes in colour. How far this was superficial and confined to the coating was difficult to determine. The tablets appeared to be blotchy also. This aspect should be examined by the expert.

409. Because of the susceptibility of drugs to alteration in composition, and in some cases disintegration by change in temperature, humidity and exposure to gases, the subject of containers is of considerable importance. Some of the modern synthetic products are sensitive to light also.

410. The traditional container for injectules, solutions and pills was glass—normally soda glass. Glass continues to be the material of choice for parenterals, as it can be sterilised with ease. The alkali in the soda glass however, may affect the pH value of the material; therefore low alkali glass is used. 96 per cent. silica glass, known as "Vicor" are super heat resistant and as such suitable for laboratory ware, crucibles, Thermocouple protection, germicidal lamps, ultraviolet filter—but cannot be used on a commercial basis as packaging materials. Therefore, the only alternative is to use Soda Glass or lead Glass for pharmaceutical packaging. The problem can be partly solved by coating the interior by silicon.

411. Plastic materials have not yet been accepted as a final choice for containers.

412. Paper and Card-Board continue to have their use for secondary packing. These are also being used increasingly as outer cover for aluminium strip packing. Aluminium strip packing has made considerable progress in recent years. Apoxi Resin is used to make the interior of aluminium strip impermeable to the action, of the drug. Collapsible tube is an ideal packing material for creams and viscous substances. It is somewhat costlier than glass but it is safer and easier to handle and has the added advantage that it cannot be easily refilled and so is somewhat proof against malpractice.

Plastics

413. Plastic prepared from Polyvinyle Chloride and Polythylene can be used for packing but Polyvinyle Chloride plastic has a disadvantage of not being free from plastisizers and additivers.

Closures

414. The present practice is to stuff the vial with cotton or paper close it with cork and cap it by metal capping. Cork was the material of choice as stopper, but as it is susceptible to a fungus and reacts to acids, its use has been restricted.

415. Rubber stoppers and plastic screw caps are now generally in use. These are secured by pilferproof caps. Ringed on cap is an unthreaded cap pressuremoulded to the bottle. Urea Formaldehyde resin caps can also be used. Urea Formaldehyde is now being produced in Calcutta. Rubber continues to be the material of choice for bottle closure as it can be penetrated with hypodermic needle without break and is self-sealing. Rubber, however, is subject to deterioration, specially synthetic rubber in adverse temperature conditions. Further, rubber absorbs materials from parenterals. Latex rubber is said to be the best.

Chapter V

(A) SOME ESSENTIAL DRUGS: PRESENT PRODUCTION AND REQUIREMENT

416. Many medical practitioners, in their evidence before the Commission, complained about the shortage of Pethidine Hydrochloride. There was also periodic shortage of the following drugs:

(1) Injection Morphine Hydrochlor,

(2) Antibiotics,

(3) Addictive Drugs,

(4) Fine Chemicals like Sodi Salicylas, Pot. Bromide.

417. Enquiries by the Commission revealed that imported drugs were periodically in short supply. For this state of affairs the present method of distribution may be responsible. Supply of drugs manufactured by foreign concern themselves, or in collaboration with Indian groups, was reported to be irregular.

418. The present system of distribution of drugs manufactured by Messrs. May and Bakers, Neopharma, Lederle, Ciba, etc., is that they appoint stockists most of whom have their shops in the Bagri Market and the Mehta Buildings, where these drugs are held in stock. Although these premises are licensed, they are not regularly inspected by the Drugs Inspectors, nor is any attempt made by the manufacturers' representatives and/or the Drug Inspectors to see that adequate supplies are maintained. This leads to artificial shortage and the creation of black market.

419. There is shortage of small-pox vaccine now and then. The Commission would like to recommend that State Government should undertake manufacture of Small Pox Vaccines of adequate potency. There is a general belief that the Russian vaccine is more potent than vaccine manufactured in the Calcutta Corporation Laboratory at Ballygunge Circular Road. The Commission was not satisfied with the arrangements that exist at present in the Calcutta Corporation manufacturing centre at Ballygunge Circular Road. Previously an experienced person was in charge, who was reported to be away in England undergoing higher training in Virology. The present incumbent has some medical practical training which is considered inadequate. Arrangement should be made to fill up the post by a fully qualified and experienced person. The Commission would strongly recommend that the Calcutta Corporation Vaccine Laboratory be taken over by the State Government.

420. In a recent case the Commission had reason to suspect the potency of Cholera Vaccine used by the local authority during a cholera epidemic. Two ampoules were procured and sent for assay to Kasauli. As against the standard of 8,000 million organisms per c.c., the report showed 2000 million organisms per c.c. only. The matter was brought to the notice of the Chief Executive Officer of the authority, who agreed to have the entire stock checked. The State Government Laboratory at Calcutta has a capacity for production of five million c.c. This should be immediately stepped up.

421. Manufacture of specialised Vaccines and Sera may be left to the private sector, provided they are first-class concerns with adequate arrangements for biological assay, modern methods of ampouling, quality control organisation and scientific storage facilities.

(B) SHORTAGE OF SOME SPECIALISED ESSENTIAL DRUGS

422. There are certain specialised and life-saving drugs which are in continuous short supply. Many of these are not manufactured in India at present. The Commission will suggest that those drugs should be imported in larger quantities through recognised stockists of repute for sale at reasonable prices.

423. A reputed medical practitioner of Calcutta confided that Heperine, a remedy for Coronary Thrombosis, was available in the blackmarket in quantities. He was afraid to name the blackmarketeer as this might stop the source of supply and result in the death of some of his patients. The plight of the poorer section of people can well be imagined. Similarly, Hirudoid ointment, Paritrate tablet, Oestroform pellets and Protocaine are not easily available.

424. The latest drugs for inoperable or advanced cases of Cancer, Hodgkins Disease and Lymphoma by chemotherapy, such as Methotreate and Velve, are also not available in the open market.

The have not yet been simulated. Nevertheless, Government should take steps to have these imported in reasonable quantities.

426. An analysis of the questionnaire regarding shortages is given below:

Analysis of reply to questionnaires from medical practitioners (1584)

AVAILABILITY OF DRUGS.

Name of drug.	Number of medical practitioners declaring non-availability.
Injection Pethidine Hydrochlor	379
Injection Morphin Hydrichlor	357
Antibiotics	69
Biological Products ..	
Sodium Salicylate ..	10
Addictive Drugs ..	
Baby Food	}
Hormone Preparations ..	}
Spirituous Drugs ..	}
Poisonous Drugs ..	}
Sulfa Drugs	}
Pot. Bromide ..	}
Physepton	
Sera	
Patent Medicines ..	
Anaesthetic Drugs ..	

Name of Drug.	Number of medical practitioners decl ring non-availability.
Olive Oil	3
Anethine	
Pulv Ipecac	4
Vaccines	
Atropine	
Glycerine	
Tranquilizers	8
Angier's Emulsion	
Hypnotic & Sedative Inj.	
P. A. S.	
Digitalis group of Drugs.	
Insulin, Barbiturates Duogynon, Tuberculin, Inj. Mydricans stilbesteel, Cod-Liver Oil, Chemicals Sulphonamides, Glucose, Gelusin, Aether Anaesthesia, Standarised Ergot, Cortisome group of drugs, Pot. Chlorate, Anti Diptheretic Serum, Salicylate Glycerine, Codeine, Omnopon, Pot Citras.	2

(C) RETAIL DISTRIBUTION OF DRUGS THROUGH HOSPITAL AND CHEMISTS AND DRUGGISTS ESTABLISHMENT

427. The evidence of Heads of Sections, or those in charge of hospitals, disclosed that they were not happy with the conditions that exist in the hospital pharmacies as the personnel there are not always quite up to the standard required. A visit to the dispensing sections of some of the better known hospitals of Calcutta disclosed insanitary conditions, illegible labelling and improper storage of medicines. The Commission understands that these Sections are not regularly inspected by persons in authority and by the Chief Medical Officer in charge. The Commission hesitates to believe that in some cases the formulations dispensed may not contain prescribed quantities of ingredients or that the costlier ingredients are totally absent. The Commission is also of the opinion that it is essential that quality of a drug should be more important than the price at which it is procured for use in hospitals. For instance, in one case "Shark Liver Oil" supplied to one hospital did not contain the oil in the bottle at all. Spot checks of random samples would be helpful and should be done more frequently. The condition at the Central Medical Stores at Sealdah should be looked into as it is reported that storage, temperature and other physical facilities are not up to the standard.

428. Calcutta is a large city with varying living conditions in its different parts. Consequently Chemists and Druggists shops in the city also vary in their standards of cleanliness, trained personnel and equipments. The Commission recommends that the minimum standards required under the Drugs Act and Rules should be strictly enforced without exception.

429. The Commission also found that in some cases the same drug in different types of packages were being sold in different parts of the city, at varying prices. This could only be possible if the drugs were sub-standard, spurious or adulterated or if they were being sold by unscrupulous dealers.

430. In the case of capsules, tamperproof seal with the manufacturer's name and the name of the drug on them would prevent misuse.

431. The Commission feels that so long the Government remains indifferent to these matters, the distributing centres will take advantage and vend sub-standard and spurious drugs.

(D) SURVEY OF EXISTING LEGISLATIONS ON DISTRIBUTION AND TRADE IN DRUGS

432. The following materials are taken from the World Health Organisation publication "Distribution of and Trade in Pharmaceutical Preparations" (1962). This survey report was originally published in the "International Digest of Health Legislation", 1962: 13: 381-466.

433. Fifty years ago pharmaceutical preparations were prescribed by the physician and prepared by the pharmacists dispensary. Then legislation was directed towards control of equality of Galenical preparations. In due course the number of pharmaceutical specialities exceeded twenty thousand. Further, because of canning of food, testing of food became equally important.

434. There are two types of legislation on the subject—one for importing countries and the other for exporting countries. For control of distribution in importing countries there should be uniformity in the definition, labelling and supply of information on physico-chemical and medicobiological aspects of the drugs. Further there should be a national control authority in the importing country.

435. The legislations on the subject have been reviewed internationally on several occasions. In 1955, the fourth General Assembly of the Pan American Medical Federation considered the question of registration of pharmaceuticals (vide W.H.O. Technical Service Publication of 1957—No. 138).

436. In manufacturing countries, new regulations have been introduced modifying existing legislations—as in the Federal Republic of Germany (1961). Belgium (1960). Netherlands (1961).

437. The legal provisions governing the pharmaceutical specialities are generally incorporated in laws which regulate trade in pharmaceutical preparations like galenicals, food, cosmetics, and in some cases medical appliances. The U.K. Acts of 1860 and 1872 legislated against fraud and adulteration of food and pharmaceutical preparations. This was followed by the Canadian Act in 1874 which specified that pharmaceutical preparations should conform to the standards laid down in the regulations. The U.S.A. followed Canada and legislated Food and Drugs Act and introduced the term "Misbranding" of pharmaceutical preparations.

438. The present system of distribution of drugs manufactured in West Bengal is satisfactory, other than those items that go through the Bagri Market or nearabout.

Chapter VI

SUMMARY OF RECOMMENDATIONS

The main recommendations made by the Commission in the body of the Report may be briefly summarised as follows:

Chapter II

(1) Supply of raw materials from indigenous sources should be developed by—

(a) Manufacture of suitable drugs from coal-tar distillation products and production of basic organic chemicals and intermediates.

(b) Exploitation of petro-chemical sources.

(c) Extension and exploitation of medicinal plants grown in State Government Plantations in the Duars, Terai and hill areas around Darjeeling, systematic investigation into the flora of Sikkim and Bhutan.

(d) Immediate establishment of State Phytochemical Plant in North Bengal for extraction of:

(i) Cafferine from tea wastes and tea prunings;

(ii) Emetine from Ipecac roots;

(iii) Ergot alkaloids, specially Ergometrine from Claviceps Purpurea;

(iv) Reserpine and allied alkaloids from Rauwolfia Serpentina Benth;

(v) Adrenaline from Catechu;

(vi) Cortisone from Dioscorea.

(e) Improvement of slaughter house and establishment of abbatoris, if necessary, for recovery of valuable animal and glandular products.

(2) Indigenous manufacture of plants and equipments should be encouraged by the State, with foreign collaboration, if necessary.

(3) The State Government should create a cadre of scientific personnel and adequate testing facilities to enable the State Drug Control Laboratories to test drugs to ensure quality control.

(4) As the existing facilities for training of technical personnel are inadequate, action should be taken for—

(a) Introducing Four Year Course in Pharmacy in the Universities;

(b) Training and refresher courses from time to time during service.

(5) (a) An expert committee should be created to report on procedure for testing toxicity, clinical trial and study of adverse effect of synthetics and drugs of animal origin.

(b) Unproved or partly proved drugs should not be permitted to be imported to India.

(c) Those manufactured in India should first be cleared by a Technical Committee and distinctively marked, as is done in France.

(d) Vigilance should be exercised by manufacturers' organisations by voluntary control as in the U.K.

(e) Expeditious dissemination of information by the Indian Medical Association of adverse effects of drugs is very desirable.

(6) The following difficulties are faced by manufacturers and every effort should be made by Government to improve conditions.

(a) Varying and inadequate pressure of the city's gas supply;

(b) Fluctuating voltage in the city's electric supply;

(c) High maintenance cost of air-conditioning plants;

(d) Unavailability of refrigerant gas;

(e) Transport difficulties;

(f) Inclusion of Basic Raw Materials in Item 28 of Tariff Schedule which is keeping prices high.

Chapter III.

(1) The present Drugs Act should be further amended for—

(a) Simplification of the definition of the term "Drug".

(b) Re-defining the terms "Misbranded", "Spurious", "Sub-standard" and "Adulterated" in relation to drugs.

(c) Substituting I.P. for B.P. or B.P.C., in Entry 4 of the schedule to the Act.

(d) Omitting Schedule F.

(2) The practice of Pharmacy should be rationalised by keeping out over 10,000 pharmacists registered under section 31(d), replacing them by qualified pharmacists.

(3) Punishment for offences under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, should be more severe.

(4) The Drug Control Administration should be under a full-time Drug Controller, assisted by Assistant Controllers, Senior Inspectors and Junior Inspectors, who should be adequate in number.

(5) The Chief Medical Officers of Health and Subdivisional Health Officers may continue as ex-officio Drug Inspectors for the present.

(6) There should be an Advisory Cell for—

(a) Advising entrepreneurs, if required, on what to do for starting manufacture of drugs.

(b) Recommending to the existing concerns methods of improvement based on analysis of inspection reports of Drug Inspectors.

(7) There should be an Intelligence Cell headed by a senior Police officer for the purpose of locating spurious manufacturing premises and reporting malpractices.

(8) There should be a Law Section which should be headed by an expert Lawyer.

(9) The Drug Control Laboratory should be an independent unit. The present state of affairs of the Laboratory should be enquired into by Government.

Chapter IV

(1) The public should be educated regarding dangerous of addiction and self-medication. Sale of aphrodisiacs should be severely restricted. Strict control over sale of Pethidine, Morphine, etc., is necessary to control addiction.

(2) Malpractice in sale is due sometimes to artificial shortage created by stockists. This should be controlled by strict enforcement of provisions of the West Bengal Drug Control Act, 1950.

(3) Malpractice in storage is more due to inadvertence and lack of knowledge than any deliberate attempt to avoid cost.

Chapter V

(1) The Calcutta Corporation Vaccine Laboratory should be taken over by the State Government.

(2) The production of Cholera Vaccine at the State Government Laboratory should be stepped up.

(3) The condition of the Central Medical Stores should be looked into.

(4) In the case of all chemists and druggists' shops, the minimum standards required under the Drugs Act and Rules should be strictly enforced without exception.

(5) Tamper-proof seals, with the manufacturer's name and name of drug in the case of capsules, will prevent misuse.

(6) The standards for packing of drugs should be specified immediately.

(7) There should be statutory compulsion on perforation of strips, separating individual tablets.

The Commission also strongly recommends that life-saving drugs which are not manufactured in this country, should be freely imported by Government.

General Recommendation

Although not strictly within the purview of the Commission in as far as its terms of reference, the Commission nevertheless wishes to suggest to the Government of West Bengal for its consideration in regard to the manufacture of drugs in the State.

There are only a few concerns now in existence that could be called medium sized, indicated by the sizes of their present plant and capital outlay. There are innumerable manufacturing units from the small individual cottage type mostly worked by such people as the East Bengal refugees, to others slightly larger but by no means could they be termed as effective manufacturing units.

There is no doubt whatsoever in the minds of the Commission that if the West Bengal Government wishes the manufacture of drugs to continue and expand in West Bengal, then it must give the industry the necessary encouragement and impetus.

This could be in many forms to suit the requirements of the various individual concerns that are already in existence as well as those who may launch into the manufacture of drugs.

First and foremost is to enable the concern to find the requisite land that would be hygienic and suitable for the manufacture of drugs. Pure water and electric power should also be made available. The land should also be so situated that transport facilities are easily available. Otherwise if housing for labour and staff are included in the capital outlay of the drug manufacturing unit, the cost of production from such a unit will be prohibitive.

The West Bengal Government should carefully consider all applications for licence for manufacture of drugs before they approve of them unlike what has been done in the past. Mere sentiment should not be only criterion.

The entrepreneurs should prove their identity as well as their past performance, if any, and also state clearly who are their collaborators, as technical experts (doctors and scientists come under this term) and/or financier.

In the case of entrepreneurs wishing to collaborate with foreign concerns, here again, the Government should look into the antecedents and precedents of such concerns, particularly past records of the foreign collaborators in their country. In every case consideration should be given to those concerns whose objects are not only to establish manufacturing concerns but to expand it as the market requirements rise.

The foreign exchange requirement by the indigenous manufacturers may have to be guaranteed by the Government of West Bengal and/or strong recommendations made to the Industrial Finance Corporation, or the Industrial Credit and Investment Corporation of India, or the Government of India. In the case of foreign collaborators this matter of foreign exchange would naturally be covered by the collaborators themselves.

There may be a third type of indigenous entrepreneurs who are already in existence and have invested a great deal of money in their organisations and who would naturally not like to collaborate with foreign concerns over a few typical drugs, as they may have to part with shares in their already existing concerns, unless of course they form a new company under a different name. For these concerns, should they wish to expand with the help of foreign technicians and/or research men, the Government of West Bengal should support their claims with the Reserve Bank for the purpose of foreign exchange control, etc. etc., in getting such men out.

It should also be borne in mind that any newcomer into the field of drug manufacture will find his cost of production during the first few years of existence, high compared to others, until he settles down, all his teething troubles solved, and production maintained at the rated capacity. Government ought not be impatient during this early stage of production.

The Commission wishes to place on record its appreciation of the work done by the Experts' Committee appointed by the Commission. Their report in *extenso*† is annexed. The Commission is in general agreement with the recommendations of the Experts' Committee, except to the extent indicated otherwise in the Report.

The Commission also wishes to place on record its appreciation of the services of the staff, whose list is given in the *appendix, but would like to mention in particular the names of Dr. N. N. Mazumdar, M.B, D.P.H., D.N., the Assistant Secretary, and Shri P. R. Choudhury, Additional Assistant Secretary.

1. (Sd.) Biren Mookerjee.
2. (Sd.) B. P. Tribedi.
3. (Sd.) Kanak Sarbadhikari.
4. (Sd.) Salil Dutt.
5. (Sd.) Abodh Kumar Sinha.
6. (Sd.) Ashima Chatterjee.
7. (Sd.) S. M. Ghosh.
8. (Sd.) K. N. Sen.
9. (Sd.) S. M. Banerji.

The 15th June 1964.

†Report has not been printed.

* Appendix has not been printed.

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